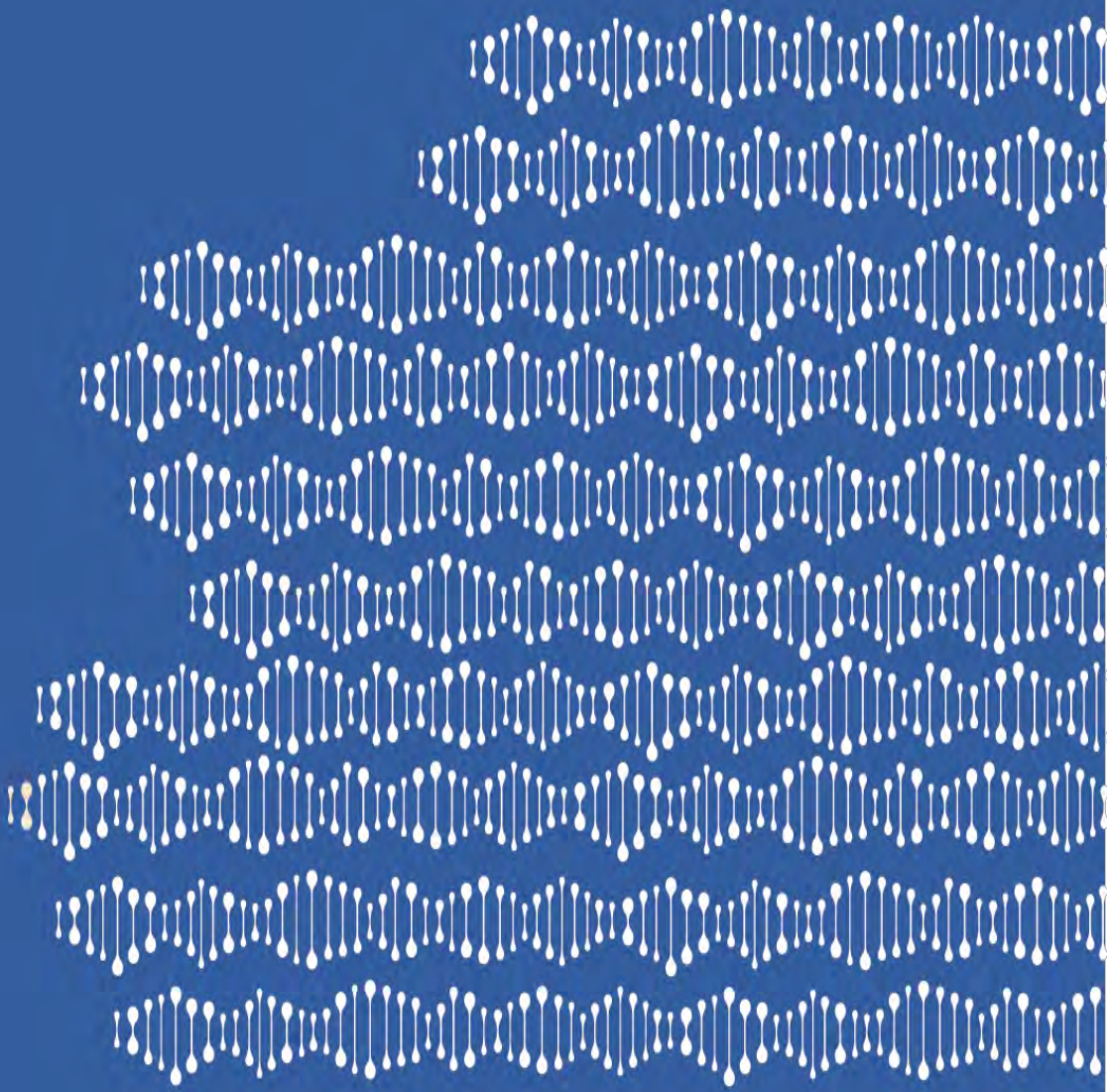
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

May 15, 2019



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

Texas Higher Education Coordinating Board
1200 E. Anderson Lane, Austin, TX 78752
Board Room 1.170

May 15, 2019
10:00 a.m.

The Oversight Committee may discuss or act on any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any purpose permitted by the Act. Anyone wishing to offer public comments must notify the Chief Executive Officer in writing prior to the start of the meeting. The Committee may limit the time a member of the public may speak.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from the February 21, 2019, meeting — Tab 1
4. Public Comment
5. Chief Executive Officer Report — Tab 2
6. Chief Compliance Officer Report — Tab 3
7. Chief Scientific Officer Report — Tab 4
   - Grant Award Recommendations
   - Proposed FY 2020 Requests for Applications for Recruitment Awards
8. Chief Prevention and Communications Officer Report — Tab 5
9. Chief Product Development Officer Report — Tab 6
10. Scientific Research and Prevention Program Committee Appointments — Tab 7
11. Advisory Committee on Childhood Cancer Appointment — Tab 8
12. University Advisory Committee — Tab 9
    - Annual Report
13. Advisory Committee on Clinical Trials — Tab 10
    - Annual Report
14. Advisory Committee on Product Development — Tab 11
    - Annual Report
15. Internal Auditor Report — Tab 12
    - Internal Audit Follow Up Procedures Report Over Post-Award Grant Contract and Monitoring
16. Amendments to 25 T.A.C. Chapters 701 – 703 — Tab 13
    - Final Order Approving Amendments to Chapter 703
    - Proposed Amendments to Chapter 703 and Authorization to Publish in *Texas Register*
17. Chief Operating Officer Report — Tab 14
18. Fiscal Year 2020 Bond Issuance Resolution — Tab 15
19. Contract Approvals — Tab 16
    - Due Diligence Services (contract amendment)

- Grant Management Support Services (contract renewal)
- Austin Convention Center Catering Contract

20. Subcommittee Business
21. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
22. Consultation with General Counsel
23. Future Meeting Dates and Agenda Items
24. Adjourn

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Summary Overview of the May 15, 2019, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the May 15, 2019, Oversight Committee meeting.

CEO Report
Wayne Roberts will present the CEO's report and address issues including personnel, status of legislation affecting CPRIT, FY19 grant award funds available, and other topics.

Chief Compliance Officer Report
Vince Burgess will report on the status of required grantee reports, financial status report reviews, desk reviews and site visits, annual compliance attestation, single audit tracking, and training.

Chief Scientific Officer Report and Grant Award Recommendations
Dr. James Willson will provide an update on the Academic Research Program, including a proposed request for recruitment applications for FY 2020, and present the Program Integration Committee's award recommendations for Recruitment of First-Time, Tenure-Track Faculty Members, Recruitment of Rising Stars, and Recruitment of Established Investigators.

CPRIT does not publicly disclose information related to the Academic Research grant applications recommended for funding until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Prevention and Communications Officer Report
Dr. Becky Garcia will update the Oversight Committee on the on the agency's prevention program. She will also report on CPRIT's communications activities.

Chief Product Development Officer Report and Grant Award Recommendations
Dr. Cindy WalkerPeach will provide an update on the Product Development Program

Advisory Committee Annual Report Presentations
CPRIT's administrative rules and the advisory committees' charters require the committees to provide updates to the Oversight Committee annually. The chairs of three CPRIT advisory committees will present their annual reports and recommendations to the Oversight Committee.

- University Advisory Committee Chair Dr. Michelle Barton
- Advisory Committee on Clinical Trials Chair Dr. Kent Osborne
- Product Development Advisory Committee Chair Dr. Jonathan MacQuitty

Appointments - Scientific Research and Prevention Programs Committee and the Advisory Committee on Childhood Cancer
Mr. Roberts has provisionally appointed five new members to CPRIT's Scientific Research and Prevention Programs Committees and one new member to the Advisory Committee on

Childhood Cancer. CPRIT's statute requires the Oversight Committee to approve the CEO's recommendations before the appointments are final.

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will provide an internal audit update and will present an internal audit report on follow up procedures over post-award grant management.

Amendments to 25 TAC Chapters 703
Cameron Eckel will present the final order approving amendments to Chapter 703 that the Oversight Committee provisionally approved at the February meeting. If approved, the amendment will become effective in June.

Ms. Eckel will also offer proposed changes to the agency's administrative rules in Chapter 703. Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute. Legal staff will bring back these rule changes to the Oversight Committee for final approval in August after the public has commented on the proposed rule changes.

Chief Operating Officer Report, Fiscal Year 2020 Bond Issuance Resolution, and Contract Approvals
Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the first quarter of FY 2019. She will also present the Fiscal Year 2020 Bond Issuance Resolution for approval by the Oversight Committee. Ms. McConnell will report recommendations for contract approvals for the following services: due diligence (budget amendment), grant management support (contract renewal), and the Austin Convention Center catering contract for the 2020 CPRIT Conference.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting
February 21, 2019

NOTE: Unless the information is confidential, the reports, presentations, and grant award information referenced in the minutes are available at http://ocmeetings.cprit.texas.gov in the "Oversight Committee Board Packet" section for the corresponding meeting date.

Call to Order – Agenda Item 1

A quorum being present, Presiding Officer Will Montgomery called the Oversight Committee to order at 10:01 a.m.

Roll Call/Excused Absences – Agenda Item 2

Committee Members Present	Committee Members Absent
Bill Rice, M.D.	Craig Rosenfeld, M.D.
Will Montgomery	
Mahendra Patel, M.D.	
Donald (Dee) Margo	
David Cummings, M.D.	
Angelos Angelou	

MOTION:
On a motion by Dr. Cummings and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve the excused absences of Dr. Rosenfeld.

Adoption of Minutes from the November 28, 2018 Meeting – Agenda Item 3 – Tab 1

MOTION:
On a motion by Dr. Cummings and seconded by Dr. Patel, the Oversight Committee unanimously voted to approve the minutes of the Oversight Committee meeting of November 28, 2018, as presented.

Public Comment – Agenda Item 4

There were no requests to provide public comment.

Grantee Presentation – Agenda Item 5 – Tab 2

Dr. Willson introduced CPRIT grantee, Hashem B El-Serag, M.D., MPH, Professor and Chair of the Department of Medicine and Director of the Texas Digestive Disease Center, Baylor College of Medicine. Dr. El-Serag reported on the work of the CPRIT-funded Texas Hepatocellular Carcinoma

Consortium (THCCC), a multidisciplinary research project aimed at reducing the burden of hepatocellular (HCC) in Texas. The consortium includes researchers from The University of Texas Southwestern Medical Center, Parkland Health and Hospital System in Dallas, Baylor College of Medicine, The University of Texas MD Anderson Cancer Center, and The University of Texas at San Antonio. Dr. El-Serag noted the inclusion of sites across Texas is to enrich the diversity and representativeness of patients, ensuring a racially and ethnically diverse cohort. Dr. El-Serag noted that prevention of HCC is the main step to reduce death and suffering and understanding the risk factors for HCC is essential for prevention. Dr. El-Serag told the Oversight Committee members that CPRIT provided an unrivaled opportunity for research and prevention of HCC.

Following his presentation, the Oversight Committee members asked Dr. El-Serag several questions regarding the development of novel biomarkers and the impact of circadian disruption as risk factor for HCC.

Chief Executive Officer Report – Agenda Item 6 – Tab 3

Mr. Roberts thanked the Higher Education Coordinating Board Commissioner for allowing CPRIT to use the Coordinating Board's location for CPRIT's meeting.

He introduced the new Chief Product Development Officer, Cindy WalkerPeach, and reported that with Dr. WalkerPeach's hiring, CPRIT has filled all 35 FTE positions.

Mr. Roberts discussed the newly released *2018 CPRIT Annual Report*, explaining it was an agency-wide effort headed up by Chief Prevention and Communications Officer Dr. Becky Garcia and her communications team. He noted that the report is available through CPRIT's new website, which went live in January.

Mr. Roberts reviewed recent legislative activity affecting CPRIT, including committee hearings for Senate Finance and House Appropriations committees. He also discussed CPRIT-specific legislation, including House Joint Resolution 12, House Bill 39 and Senate Bill 200. Mr. Roberts ended his report with an update of funds available.

Presiding Officer Montgomery recognized the Communications and IT staff for their work on CPRIT's new website, including an "honorable mention" to IT staff member Jim Hurlbut for maintaining regular IT operations during the intense focus on preparing the new website.

Chief Compliance Officer Report – Agenda Item 7 – Tab 4

Mr. Burgess presented the Compliance Report for the past quarter's activities. He stated that the number of delinquent reports started out the quarter at a larger-than-expected delinquency rate but ended the quarter with 32 delinquent reports, just above the target goal of 28 or less reports.

Mr. Burgess reported that the Compliance Program overhauled CPRIT's annual compliance training, splitting the training into separate webinars for each of the three program areas: Academic Research, Prevention, and Product Development. Doing so allows for a more interactive experience and focus on topics specific to each program. CPRIT will hold its first training series for 2019 on March 6 and March 7.

Following his Compliance Officer Report, Mr. Burgess certified that the review process for the Academic Research, Prevention, and Product Development Research grant awards recommended for consideration by the Oversight Committee complied with CPRIT's statute and administrative rules.

Chief Scientific Officer Report and Award Recommendations – Agenda Item 8 – Tab 5

Chief Scientific Officer James Willson presented the Academic Research Program, referring members to pages 5-1 and 5-2 of the Oversight Committee board packet. Following up on a request from the Oversight Committee, he also provided an overview of CPRIT's recruitment of outstanding cancer researchers to Texas (page 5-3 – 5-5 of the Oversight Committee board packet.)

Dr. Willson then presented the Academic Research Program award slates recommended by the CPRIT Scientific Review Council (SRC) and the Program Integration Committee (PIC) (Proposed Grant Award book, pages 12-26.) The slates include 42 awards from seven grant mechanisms totaling $52,856,653. He noted that 19% of the awards supported childhood cancer research projects. Dr. Willson also reported that the PIC recommended to defer action until August for ten applications recommended by the SRC with overall scores of 3.0 and higher to ensure that there are enough funds for the Academic Research Program awards for 19.2 cycle.

Cycle 19.1 Recommended Academic Research Awards

App ID	Award Mechanism	Meeting Overall Score	Application Title	PI	PI Organization	Recommended Budget
RP190067	IIRACT	**1.1**	Improving T-Cell Therapy of Neuroblastoma With a Novel Cytokine Modulator: A Phase 1 Clinical Trial	Rooney, Cliona M	Baylor College of Medicine	$1,499,252
RP190417	IIRA	**1.2**	Decoding the Pathogenic Roles of Noncoding Variants in Hematopoietic Malignancies	Xu, Jian	The University of Texas Southwestern Medical Center	$900,000
RP190049	IIRACT	**1.2**	Noninvasive Detection and Assessment of Therapy Response in Multiple Myeloma Using Whole-Body MRI	Madhuranthakam, Ananth J	The University of Texas Southwestern Medical Center	$1,189,577
RP190451	IIRA	**1.3**	Comprehensive Evaluation of Functional Enhancers in Breast Cancer Risk Susceptibility Loci	Hon, Gary C	The University of Texas Southwestern Medical Center	$896,892
RP190022	IIRAP	**1.4**	A Randomized, Controlled Trial Comparing the Immunogenicity of 2 Doses Versus 3 Doses of the 9-Valent HPV Vaccine in Males and Females 15 to 26 Years of Age	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$1,491,473
RP190207	IIRA	**1.9**	Understanding the Role of FBXW7 as a Defining Driver of Uterine Carcinosarcoma	Castrillon, Diego H	The University of Texas Southwestern Medical Center	$881,433
RP190012	IIRA	**1.9**	Berberine in Prevention of Biochemical Recurrence	Kumar, Addanki P	The University of Texas Health Science Center at San Antonio	$900,000

RP190400	IIRACCA	**1.9**	Utilization of Imaging and Serum Biomarkers to Predict the Development of Cardiac Dysfunction in Childhood Cancer Survivors	Noel, Cory V	Baylor College of Medicine	$1,192,412
RP190043	IIRA	**2.0**	Mitochondrial Metabolism and RNA Methylation in Cancer	Aguiar, Ricardo	The University of Texas Health Science Center at San Antonio	$900,000
RP190398	IIRA	**2.0**	Targeting the Mechanism of Hyperactive FOXA1 in Transcriptional Reprogramming Toward Endocrine Resistance and Metastasis in Breast Cancer	Schiff, Rachel	Baylor College of Medicine	$899,566
RP190019	IIRA	**2.0**	Lymphatic Delivery of Checkpoint Blockade Inhibitors for More Effective Immunotherapy	Sevick, Eva M	The University of Texas Health Science Center at Houston	$900,000
RP190278	IIRA	**2.0**	Investigating Brain Tumor Drug Delivery by Optical Modulation of Blood-Brain Barrier Using Plasmonic Nanobubbles	Qin, Zhenpeng	The University of Texas at Dallas	$900,000
RP190192	IIRA	**2.1**	Pharmacological Targeting of the IRE1/XBP1 Pathway for Triple-Negative Breast Cancer Therapy	Koong, Albert	The University of Texas M. D. Anderson Cancer Center	$900,000
RP190236	IIRA	**2.1**	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,397
RP190279	IIRAP	**2.2**	Mechanisms of Prevention of Polycyclic Aromatic Hydrocarbon (PAH)–Mediated Lung Carcinogenesis by Omega-3 Fatty Acids	Moorthy, Bhagavatula	Baylor College of Medicine	$899,151
RP190160	IIRACT	**2.2**	Interleukin-15– and -21–Armored Glypican-3–Specific CAR T Cells for Patients With Hepatocellular Carcinoma	Heczey, Andras	Baylor College of Medicine	$2,400,000
RP190107	IIRACB	**2.3**	Digital Pathology Analysis for Lung Cancer Patient Care	Xiao, Guanghua	The University of Texas Southwestern Medical Center	$885,185
RP190256	IIRA	**2.4**	Role of S1PR1 in Exercise-Induced Tumor Vascular Remodeling	Schadler, Keri	The University of Texas M. D. Anderson Cancer Center	$899,992
RP190301	IIRA	**2.4**	Biophysical Mechanisms of Human Microhomology-Mediated End Joining	Finkelstein, Ilya J	The University of Texas at Austin	$900,000
RP190077	IIRA	**2.4**	Molecular Action of Phospho-BRD4–	Chiang, Cheng-Ming	The University of Texas	$864,000**

			Targeting Compounds in Breast Cancer		Southwestern Medical Center	
RP190435	IIRA	**2.4**	Modulating Cardiomyocyte DNA Damage in Response to Genotoxic Stress	Sadek, Hesham	The University of Texas Southwestern Medical Center	$900,000
RP190295	IIRA	**2.4**	Targeting Hypomethylating Resistance in Myelodysplastic Syndromes	Colla, Simona	The University of Texas M. D. Anderson Cancer Center	$900,000***
RP190326	IIRA	**2.4**	Therapeutic Potential of T Follicular Helper Cells for Melanoma Treatment	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	$900,000
RP190218	IIRA	**2.5**	Deciphering the Underlying Biology and Translational Relevance of PD-L2	Curran, Michael A	The University of Texas M. D. Anderson Cancer Center	$900,000
RP190252	IIRA	**2.5**	A Novel Therapy Targeting Prostate Cancer–Induced Aberrant Bone Formation	Lin, Sue-Hwa	The University of Texas M. D. Anderson Cancer Center	$900,000
RP190210	IIRAP	**2.5**	Improving the Quality of Smoking Cessation and Shared Decision-Making for Lung Cancer Screening: A Cluster Randomized Trial	Volk, Robert J	The University of Texas M. D. Anderson Cancer Center	$1,499,527
RP190132	IIRACCA	**2.5**	Multiomic Biomarker Discovery for Therapy-Related Neurocognitive Impairment in Childhood Acute Lymphoblastic Leukemia	Brown, Austin L	Baylor College of Medicine	$1,187,006
RP190385	IIRACCA	**2.6**	Growth Signaling in Ewing Sarcoma	Shiio, Yuzuru	The University of Texas Health Science Center at San Antonio	$1,200,000
RP190360	IIRACT	**2.6**	Immunotherapeutic Targeting of SLC45A2 for Treatment of Uveal Melanoma	Yee, Cassian	The University of Texas M. D. Anderson Cancer Center	$2,399,991
RP190029	IIRA	**2.7**	The EZH2 Deubiquitinase ZRANB1 as a Therapeutic Target in Breast Cancer	Ma, Li	The University of Texas M. D. Anderson Cancer Center	$900,000
RP190131	IIRA	**2.7**	Neoadjuvant Treatment Response Monitoring of Breast Cancer With Molecular Photoacoustic Imaging	Bouchard, Richard	The University of Texas M. D. Anderson Cancer Center	$895,907
RP190235	IIRA	**2.8**	Role of Long Noncoding RNAs in Breast Cancer: Identification, Characterization, and Determination of Molecular Functions	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,747

RP190002	IIRACCA	**2.8**	Development of a Precision Drug to Target STAG2 (SA2)–Mutant Ewing Sarcoma	Pati, Debananda	Baylor College of Medicine	$1,189,218
RP190233	IIRACCA	**2.8**	Improving Safety and Efficacy of Amino Acid Depletion Therapy for Acute Lymphoblastic Leukemia Using Translatable Nanotechnology	Lux, Jacques	The University of Texas Southwestern Medical Center	$1,200,000
RP190454	IIRA	**2.9**	Characterization of CTCF-Mediated 3D Genome Organization and Transcriptional Regulation in Metastatic Prostate Cancer	Mani, Ram S	The University of Texas Southwestern Medical Center	$900,000
RP190211	IIRA	**2.9**	Assessments of Tumor Perfusion With Dynamic Contrast–Enhanced Multispectral Optoacoustic Tomography	Pagel, Mark D	The University of Texas M. D. Anderson Cancer Center	$886,927

An Oversight Committee Member noted that only one award in this cycle targets liver cancer. Dr. Willson updated the members on CPRIT's *Collaborative Action Program to Reduce Liver Cancer Mortality in Texas* RFAs that closed January 30. He explained that in May the review panels will evaluate the applications submitted in response to these targeted RFAs and he will bring recommended awards to the Oversight Committee in August.

Recommended Recruitment Awards

Rank	App ID	Candidate	Mechanism	Organization	Budget	Overall Score
1	RR190023	Uri Ben-David, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas M. D. Anderson Cancer Center	$2,000,000	1.0
2	RR190025	Julian West, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	Rice University	$2,000,000	1.6
3	RR190020	Sangeetha Reddy, M.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas Southwestern Medical Center	$2,000,000	2.0
4	RR190027	Joshi Alumkal, M.D.	Recruitment of Rising Stars	The University of Texas Southwestern Medical Center	$4,000,000	2.0
5	RR190029	Ravikanth Maddipati, M.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas Southwestern Medical Center	$2,000,000	2.2
6	RR190021	Di Zhao, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas M. D.	$2,000,000	2.8

				Anderson Cancer Center		

Compliance Certification and Conflict of Interest Notification

Presiding Officer Montgomery reminded members that Mr. Burgess had certified the proposed Academic Research Program award slates. He noted that no Oversight Committee member reported a conflict of interest with any applications under consideration.

MOTION:
On a motion made by Mr. Angelou and seconded by Mr. Margo the Oversight Committee unanimously voted to approve the PIC's recommendations for the following Academic Research Program grant award slates:

- Recruitment of First-Time, Tenure-Track Faculty Members
- Recruitment of Rising Stars
- Recruitment of Established Investigators
- Individual Investigator Research Awards
- Individual Investigator Research Awards for Cancer in Children and Adolescents
- Individual Investigator Research Awards for Clinical Translation
- Individual Investigator Research Awards for Computational Biology
- Individual Investigator Research Awards for Prevention and Early Detection

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice the Oversight Committee unanimously voted to approve the delegation of contract negotiation authority to CPRIT's CEO and staff and authorized the CEO to sign the contracts on behalf of CPRIT.

Chief Prevention and Communications Officer Report and Award Recommendations – Agenda Item 9 – Tab 6

Chief Prevention and Communications Officer Becky Garcia updated members on the Prevention Program activities and presented the seven Prevention Program projects, representing three grant mechanisms, recommended by the Prevention Review Council and PIC totaling $12,328,462. Dr. Garcia reported that all the recommended applications address one or more of the Prevention Program priorities.

Cycle 19.1 Recommended Prevention Program Awards

App. ID	Mech	Application Title	PD	Organization	Score	Rank Order	Budget
PP190009	TCL	Expanding Tobacco Use in Northeast Texas	Prokhorov, Alexander V	The University of Texas M.D. Anderson Cancer Center	2.1	1	$1,499,956
PP190027	TCL	Engaging Oral health Providers for Evidence-Based Tobacco Cessation	Jones, Daniel L	Texas A&M University System Health Science Center	2.7	2	$1,499,871
PP190004	EPS	Partnering with schools and clinics to expand a highly successful HPV vaccination program for 9 - 17-year-olds from Medically Underserved Areas	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	1.5	3	$2,499,411
PP190021	EPS	Access to Breast and Cervical Care For West Texas (ABC24WT)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	1.6	4	$2,430,998
PP190023	EPS	School-based Human Papillomavirus Vaccination Program in the Rio Grande Valley: Continuation and Expansion to Hidalgo County	Rodriguez, Ana M	The University of Texas Medical Branch at Galveston	1.9	5	$1,969,731
PP190014	EPS	Expansion of cervical cancer prevention services to medically underserved populations through patient outreach, navigation & provider training/telementoring	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	2.6	6	$2,128,529
PP190041	DI	Adolescent Vaccination Program: Online Decision Support for Adoption of Evidence-Based HPV Vaccination Strategies by Texas Pediatric Clinics	Shegog, Ross	The University of Texas Health Science Center at Houston	2.0	7	$299,966

EBP: Evidence-Based Cancer Prevention Services
EPS: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations
TCL: Tobacco Control and Lung Cancer Screening
DI: Dissemination of CPRIT-Funded Cancer Control Interventions

An Oversight Committee member asked about the success reported by Dr. Berenson's previous project. Dr. Garcia attributed the high completion rate for the HPV vaccination series to several factors including that patients are seen in a system of clinics that implemented standing orders as well as intensive patient follow-up efforts.

An Oversight Committee member asked for data relating to cancer precursors and cancers detected resulting from Dr. Rahman's project. Dr. Garcia indicated that she did not have the information immediately accessible but would follow up after the meeting. [Dr. Garcia provided the following information to the member after the meeting: In the first year of the project (September 1, 2017 - August 31, 2018), 1,736 women received breast screening and diagnostic services and 334 women received cervical screening and diagnostic services. During this year, the screening and diagnostic services detected 12 breast cancers, one cervical cancer and 23 cases of cervical cancer dysplasia.]

Compliance Certification and Conflict of Interest Notification

Presiding Officer Montgomery reminded members that Mr. Burgess had certified the proposed Prevention Program award slates. He noted that no Oversight Committee member reported a conflict of interest with any applications under consideration.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice the Oversight Committee unanimously voted to approve the PIC's recommendations for the following Prevention Program award slates:

- Tobacco Control and Lung Cancer Screening
- Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations
- Dissemination of CPRIT-Funded Cancer Control Interventions.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice the Oversight Committee unanimously voted to approve the delegation of contract negotiation authority to CPRIT's CEO and staff and authorized the CEO to sign the contracts on behalf of CPRIT.

Proposed Plan for RFAs for FY 2020 Cycle 1

Dr. Garcia presented the FY 2020 Cycle 1 RFA release schedule and timeline (page 7-2 in the Oversight Committee board packet) for consideration. The proposed RFAs in the schedule include Evidence-Based Cancer Prevention Services, Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations, Tobacco Control and Lung Cancer Screening, and Dissemination of CPRIT-Funded Cancer Control Interventions.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the Prevention Program's plan for proposed RFAs for the first cycle of FY 2020.

Communications Report

Dr. Garcia reported that CPRIT received three proposals for the 2020 CPRIT conference venue. She also introduced a video of CPRIT highlights from 2018.

Chief Product Development Officer Report – Agenda Item 10 – Tab 7

Interim Chief Product Development Research Officer Kristen Doyle provided an overview of the Product Development Research Program activities and the grant award recommendations for FY 2019 Cycle 1 (19.1). She referred members to her memo included in the Oversight Committee board packet at Tab 7.

In her presentation of the five award recommendations from the 19.1 review cycle, Ms. Doyle noted that three companies recommended for awards, Allterum Therapeutics, Icell Kealex Therapeutics, and Cell Medica, must address specific IP issues prior to executing award contracts. Ms. Doyle also

reported that the Product Development Review Council has not taken final action on two companies that underwent due diligence in the 19.1 review cycle while the companies provide more information.

Cycle 19.1 Recommended Product Development Program Awards

Rank	App ID	Mech.	Company Name	Project	Maximum Budget	Overall Score
1	DP190027	RELCO	Hummingbird Bioscience Pte. Ltd	A First-in-Class Anti-VISTA Monoclonal Antibody for the Treatment of MDSC-Mediated Suppression of Antitumor Immunity in Solid Tumors and Lymphomas	$13,116,095	2.0
2	DP190025	SEED	Allterum Therapeutics, LLC	Preclinical Development of a Novel T-ALL Therapeutic Antibody	$2,912,313	2.2
3	DP190020	SEED	Icell Kealex Therapeutics, LLC	Development of a Novel Oncolytic Vaccinia Virus Varian Suitable for Systemic Delivery	$3,000,000	2.5
4	DP190021	TXCO	Cell Medica	Off-the-Shelf CAR-NKT Cells for Treatment of Solid and Hematological Malignancy	$8,742,509	3.1
5	DP190018	RELCO	Instapath Inc.	Rapid Pathology Evaluation System for Biopsies	$3,000,000	2.2
				TOTAL	$30,770,917	

RELCO: Relocation Company Product Development Research Award
TXCO: Texas Company Product Development Research Award
SEED: Seed Awards for Product Development Research

Compliance Certification and Conflict of Interest Notification

Presiding Officer Montgomery reminded members that Mr. Burgess had certified the proposed Product Development award slates. He noted that no Oversight Committee member reported a conflict of interest with any applications under consideration.

MOTION:
On a motion made by Mr. Angelou and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the five PIC recommendations for the following grant award slates:

- Texas Company Product Development Research Awards
- Company Relocation Product Development Research Awards
- Seed Awards for Product Development Research

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the delegation of contract negotiation authority to CPRIT's CEO and staff and authorized the CEO to sign the contracts on behalf of CPRIT.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted pursuant to the General Appropriations Act, Article IX, Section 4.03(a) to authorize CPRIT to disburse grant funds via advance payments to DP190027, DP190025, DP190020, DP190021, and DP190018 upon execution of the award contracts and the successful completion of tranches.

Following the vote to approve the award recommendations, Ms. Doyle presented the proposed FY 2020 RFAs, which include the Texas Company, Relocation Company and Seed Company Awards for Product Development Research.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the proposed fiscal year 2020 Cycle 1 RFAs and timeline as recommended by Ms. Doyle.

Advisory Committee on Childhood Cancer Annual Report – Agenda Item 11 – Tab 8

Dr. Willson introduced Dr. Stephen Skapek, Chair of the Advisory Committee on Childhood Cancer (ACCC). Dr. Skapek is Professor of Pediatrics and Director of the Division of Hematology/Oncology at The University of Texas Southwestern Medical Center.

Dr. Skapek presented the ACCC FY 2018 annual report and recommendations to the Oversight Committee (Tab 8 in the Oversight Committee board packet) and provided an overview of the ACCC's mission and member representation. He discussed the success of CPRIT's commitment to childhood cancers, as evidenced by the funding of 152 research projects focused on childhood cancer with grant funding exceeding $250 million dollars, representing approximately 12% of the total CPRIT funding. Dr. Skapek highlighted notable examples in the past year that included projects focused on childhood brain tumors, leukemia, and bone and soft tissue sarcomas, all diseases for which a better understanding of the disease biology can lead to breakthroughs in the clinic. He noted that CPRIT awarded grants to institutions across the state. Additionally, Dr. Skapek noted that in 2018 CPRIT's recruitment awards brought two new pediatric researchers to Texas, Dr. John Powers (The University of Texas at Austin) and Dr. Kenneth Chen (The University of Texas Southwestern Medical Center). Dr. Skapek applauded CPRIT for supporting childhood cancer research which continues to position Texas to lead the nation.

Scientific Research and Prevention Program Committee Appointments – Agenda Item 12 – Tab 9

Mr. Roberts presented his ten new appointments to CPRIT's Scientific Research and Prevention Programs Committees. Mr. Roberts noted that CPRIT included the appointees' bio sketches in the meeting materials and explained that the Nominations Subcommittee recommended that that the Oversight Committee vote to approve the appointments.

MOTION:
On a motion by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the new Scientific Research Program Committee appointments.

University Advisory Committee Appointments - Agenda Item 13 – Tab 10

Mr. Roberts informed members that Southern Methodist University appointed Dr. Steven Currall to the University Advisory Committee.

Internal Auditor Report – Agenda Item 14 – Tab 11

Presiding Officer Montgomery recognized CPRIT's internal auditor, Alyssa Martin with Weaver and Tidwell. Ms. Martin presented the internal audit reports on state reporting and budget and planning as well as the State Auditor's Office (SAO) follow-up report on performance measures. She reported there were no findings from the budget and planning internal audit and two findings from the state reporting audit. In addition, Weaver concluded that all three findings from the SAO's 2017 Audit Report on Performance Measures were fully remediated.

Ms. Martin noted that the audit team will proceed with performing field work and testing for the four follow-up audits with open findings (Information Security, Communications, Post-Award Grant Monitoring and Procurement and P-Cards) in March and April and report on progress at the next committee meeting. She directed the committee's attention to the Internal Audit Tracking Schedule on page 11-3 of the Oversight Committee board packet and noted that there has been great progress in closing findings by CPRIT staff.

MOTION:
On a motion by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the Internal Audits and Follow-Up Report.

Amendments to 25 T.A.C. Chapters 703 – Agenda Item 15 – Tab 12

CPRIT Staff Attorney Cameron Eckel presented the final order approving amendments to Chapter 703 that the Oversight Committee provisionally approved at the November meeting. Ms. Eckel also presented proposed changes to the agency's administrative rules in Chapter 703 for publication in the *Texas Register*. She noted that the Oversight Committee will consider the proposed changes for final approval in May.

MOTION:
On a motion by Mr. Margo and seconded by Dr. Patel, the Oversight Committee unanimously voted to approve the final orders adopting rules changes to the Texas Administrative Code Chapters 703.

MOTION:
On a motion by Mr. Margo and seconded by Dr. Patel, the Oversight Committee unanimously voted to approve the publication of the proposed changes to the Texas Administrative Code Chapter 703 in the *Texas Register*.

Chief Operating Officer Report – Agenda Item 16 – Tab 13

Chief Operating Officer Heidi McConnell directed members to tab 13 in the Oversight Committee board packet and presented her report.

Subcommittee Business – Agenda Item 17

Presiding Officer Montgomery informed members that he resigned as a member of the Audit Subcommittee via a letter to the Presiding Vice Chair Margo. He noted that the Oversight Committee voted to appoint Dr. David Cummings to the Audit Subcommittee in November.

Compliance Investigation Pursuant to Health & Safety Code 102.2631 – Agenda Item 18
Consultation with General Counsel – Agenda Item 19

Presiding Officer Montgomery announced the committee would go into closed session pursuant to Texas Open Meetings Act Section 551.071 and Texas Health and Safety Code Section 102.2631 to discuss an ongoing compliance investigation and to receive advice from counsel.

Closed session at 12:28 pm.

Reconvened in open session at 12:58 pm.

Future Meeting Dates and Agenda Items – Agenda Item 20

The Oversight Committee will meet Wednesday, May 15, 2019 at the Texas Higher Education Coordinating Board.

Adjourn – Agenda Item 21

MOTION:
There being no further business, the Oversight Committee unanimously approved Presiding Officer Montgomery's motion to adjourn that was seconded Mr. Angelou.

Meeting adjourned at 12:59 p.m.

_____ _____

Signature Date

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 5, CHIEF EXECUTIVE OFFICER REPORT
DATE:	MAY 6, 2019

As of this writing the Chief Executive Officer's Report for the May 15, 2019, Oversight Committee will consist of the following items:

- Personnel update
- Status of legislation affecting CPRIT
  - *House Bill 1* (General Appropriations Act)
  - *House Joint Resolution 12* (Zerwas)—Authorizes submitting approval of a second $3 billion in General Obligation Bonds for CPRIT at the November 5, 2019, general election
  - *House Bill 39* (Zerwas) / *Senate Bill 438* (Nelson)—Companions, remove the restriction against new grant awards in FY 2023 if GO bonds are authorized or another funding source is used for FY 2023 and beyond
  - *House Bill 1680* (Paddie) / *Senate Bill 619* (Birdwell)—Companions, as introduced both bills moved CPRIT's sunset review from FY 2023 to FY 2021
  - *House Bill 2570* (Zerwas)—Extends the period during which CPRIT can use any non-bond grant appropriations from three years to eight years
  - *Senate Bill 2015* (Fallon)—Establishes a pediatric cancer research license plate, "Kids Shouldn't Have Cancer"
  - *House Bill 3147* (Parker)—Establishes a clinical trial participation program not necessarily at CPRIT but authorizes CPRIT to use grant funds to reimburse patient expenses associated with clinical trial participation including transportation, lodging, travel, parking and tolls, and other costs considered appropriate
  - *Senate Bill 2014* (Fallon)—Authorizes voluntary contributions for pediatric cancer research when applying for a motor vehicle title; registering or renewing a motor vehicle; applying for a special license plate and applying or renewing a driver's license or personal ID certificate

- *Senate Bill 200* (Schwertner)—Requires CPRIT to develop a plan for self-sufficiency once the 2007 GO bond authorization expires

- Facilities and Capitol Complex Construction
- FY 2019 Grant Awards Funds Available (attached)

Other topics may be added as warranted.

In addition, for your reference copies of the March 2019 and April 2019 CPRIT Activities Updates previously provided to you are included at the end of this tab. These reports are done in months in which the Oversight Committee does not meet.

*****

CPRIT has awarded **1,372** grants totaling **$2.260 billion**

- 216 prevention awards totaling $235.5 million
- 1,156 academic research and product development research awards totaling $2.025 billion

Of the $2.025 billion in academic research and product development research awards,

- 31.1% of the funding ($630.2 million) supports clinical research projects
- 25.2% of the funding ($510.2 million) supports translational research projects
- 26.3% of funding ($532.0 million) supports recruitment awards
- 14.4% of the funding ($292.7 million) supports discovery stage research projects
- 3.0% of funding ($59.9 million) supports training programs.

CPRIT has 8 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 4 Academic Research
- 1 Prevention

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2019

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards			4			54							58	
New Grant Contracts Signed	3	29	11	2	9	11	10	20					95	
New Grant Contracts In Negotiation			12			28							40	
Grant Reimbursements Processed (#)	215	155	151	117	135	195	186	169					1,323	
Grant Reimbursements Processed ($)	$ 24,200,640	$ 35,131,951	$ 8,541,059	$ 11,659,905	$ 15,228,234	$ 22,212,539	$ 18,347,474	$ 18,652,475					$ 153,974,277	
Revenue Sharing Payments Received	$ -	$ -	$ 158,052	$ -	$ 15,000	$ 32,500	$ 2,020	$ 27,678					$ 235,250	$ 3,656,803
Total Value of Grants Contracted ($)	$ 21,386,494	$ 63,467,857	$35,654,020	$ 2,200,000	$ 18,649,550	$ 38,046,886	$ 24,674,573	$ 22,820,536					$ 226,899,916	
Grants Awarded (#)/ Applications Rec'd (#)	13%	13%	13%	13%	13%	17%	17%	17%						
Debt Issued ($)/Funding Awarded ($)	74%	74%	73%	73%	73%	70%	70%	70%						
Grantee Compliance Trainings	3	1	2	2	1	1	1	2					13	
Grantee Compliance Monitoring Visits	0	3	0	3	2	1	2	1					12	
Awards with Delinquent Reimbursement Submission (FSR)			0			1								
Awards with Delinquent Matching Funds Verification			0			3								
Awards with Delinquent Progress Report Submission			2			1								
IA Agency Operational Recommendations Implemented	0	0	0	0	0	0	0	0						
IA Agency Operational Recommendations In Progress	9	9	9	9	9	9	9	9						
Open RFAs	10	9	12	16	15	7	8	8						
Prevention Applications Received	19	0	0	2	0	28	0	0					49	844
Product Development Applications Received	0	0	0	0	28	0	0	0					28	491
Academic Research Applications Received	7	2	2	5	168	7	9	16					216	6,894
Help Desk Calls/Emails	111	131	83	138	270	202	109	134					1,178	
MISSION														
ACADEMIC RESEARCH PROGRAM														
Number of Research Grants Announced (Annual)	0		4			42							46	
Recruited Scientists Announced														236
Recruited Scientists Accepted														175
Recruited Scientists Contracted	`													167
Published Articles on CPRIT-Funded Projects (#)														
Jobs Created & Maintained (#)														
Trainees in CPRIT-Funded Training Programs (#)														
Clinical Studies (#)														109

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2019

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Number of Patents Resulting from Research														
Number of Patent Applications														
Number of Investigational New Drugs														
PRODUCT DEVELOPMENT RESEARCH PROGRAM														
Number of Product Development Grant Announced (Annual)			0			5							5	
Life Science Companies Recruited (in TX)														9
Published Articles on CPRIT-Funded Projects														
Number of Jobs Created & Maintained														515
Clinical Trials (#)														15
Number of Patents Resulting from Research														
Number of Patent Applications														
Number of Investigational New Drugs														
PREVENTION PROGRAM														
Number of Prevention Grants Announced (Annual)			0			7							7	
People Served by CPRIT-Funded Prevention and Control Activities			223,464			241,337							464,801	
People Served through CPRIT-Funded Education and Training			136,707			165,883							302,590	
People Served through CPRIT-Funded Clinical Services			86,757			75,454							162,211	
TRANSPARENCY														
Total Website Hits (Sessions)	6,200	6,300	5,300	4,900	8,700	9,100	6,900	7,400					54,800	
Total Unique Visitors to Website (Users)	4,700	4,700	3,900	3,500	6,100	6,200	4,800	5,100					39,000	

FY 2019 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated Funds	$ 28,022,956	$ 255,297,292		$ 16,679,752	$ 300,000,000
Approved Adjustment to Operating Budget		$ (547,031)		$ 547,031	
Appropriations Transfer to DSHS		$ (2,969,554)		$ 2,969,554	
Adjusted Appropriations	$ 28,022,956	$ 251,780,707		$ 20,196,337	$ 300,000,000
Total Available for All Grants			$ 279,803,663		
1% of Total Available Grant Funding			$ 2,798,037		
Adjusted Grant Award Funding	28,022,956	$ 248,982,670			$ 277,005,626

	Prevention Grants	Academic Research Grants	PD Research Grants			
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	$ 28,022,956	$ 176,246,495	$ 75,534,212		$ 279,803,663	
Total Available for Grant Awards Incorporating 1% Grant Funding Buffer	$ 28,022,956	$ 174,287,869	$ 74,694,801		$ 277,005,626	
Announced Grant Awards						
11/28/18 AR Recruitment Awards (4)	$ -	$ 16,000,000	$ -			LN 1/8/2019
IIR Awards (23)	$ -	$ 20,623,861	$ -			LN 4/29/2019
IIRA-Childhood and Adolescent Cancer (5)	$ -	$ 5,968,636	$ -			LN 4/29/2019
IIRA-Computational Biology (1)	$ -	$ 885,185	$ -			LN 4/29/2019
IIRA-Clinical Translation (4)	$ -	$ 7,488,820	$ -			LN 4/29/2019
IIRA-Prevention and Early Detection (3)	$ -	$ 3,890,151	$ -			LN 4/29/2019
Recruitment Awards (6)	$ -	$ 14,000,000	$ -			LN 4/29/2019
PDR Relocation Award	$ -	$ -	$ 13,116,095			LN 4/29/2019
PDR SEED Awards (3)	$ -	$ -	$ 8,912,313			LN 4/29/2019
PDR Texas Company Award	$ -	$ -	$ 8,742,509			LN 4/29/2019
Prevention Awards	$ 12,328,462	$ -	$ -			LN 4/29/2019
Announced Grant Award Subtotal	$ 12,328,462	$ 68,856,653	$ 30,770,917	$ -	$ 111,956,032	
Grant Award Adjustments						
Declined Recruit Award (BCM-Satpathy) 11/2018 Slate	$ -	$ (2,000,000)	$ -		$ (2,000,000)	LN 2/5/2019 RR190003
Declined Recruit Award (UTSW-Alumkal) 2/2019 Slate		$ (4,000,000)			$ (4,000,000)	LN 4/29/2019 RR190027
Declined Recruit Award (UTMDACC-Ben-David) 2/2019 Slate		$ (2,000,000)			$ (2,000,000)	LN 4/29/2019 RR190023
Revised Grant Award Subtotal	$ 12,328,462	$ 60,856,653	$ 30,770,917		$ 103,956,032	
Available Funds as of April 26, 2019	$ 15,694,494	$ 113,431,216	$ 43,923,884		$ 173,049,594	
Pending Grants-PIC Recommendations						
Recruitment Awards (10)	$ -	$ 31,562,462	$ -			
	$ -	$ -	$ -			
Pending Award Subtotal	$ -	$ 31,562,462	$ -		$ 31,562,462	
Total Potential Grant Funding Committed	$ 12,328,462	$ 92,419,115	$ 30,770,917		$ 135,518,494	
Available Funds as of April 30, 2019	$ 15,694,494	$ 81,868,754	$ 43,923,884		$ 141,487,132	
1% Grant Funding Buffer	$ -	$ 1,958,626	$ 839,411		$ 2,798,037	

Operating Budget Detail	
Indirect Administration	$ 3,577,683
Grant Review & Award Operations	$ 13,649,100
Subtotal, CPRIT Operating Costs	$ 17,226,783
Cancer Registry Operating Cost Transfer	$ 2,969,554
Total, Operating Costs	20,196,337

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE MARCH 2019
DATE:	MARCH 29, 2019

Topics in this memo cover the month of March 2019 and include recent milestones in our fight against cancer, a staffing summary, CPRIT outreach efforts, legislative session activities, and updates from Compliance, Programs, and Operations.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- Peloton Therapeutics recently secured $150 million in a Series E financing round. The funding will support Peloton's Phase 3 clinical trial of PT2977 for patients with metastatic renal cell carcinoma and the clinical development of this drug candidate in Von Hippel-Lindau disease, a familial cancer syndrome for which there are currently no approved drugs. Peloton Therapeutics received a CPRIT Product Development Research Award in June 2010.

- On February 18 Hummingbird Bioscience announced that Dr. James Allison and Dr. Padmanee Sharma, MD have joined its Scientific Advisory Board. Dr. Allison, a CPRIT Scholar, shared the 2018 Nobel Prize in Medicine for his discovery of cancer therapy by inhibition of negative immune regulation. A scientific leader in oncology, specializing in renal, bladder and prostate cancer, Dr. Sharma focuses on resistance mechanisms within the immune system that impact anti-tumor responses. CPRIT approved a $13.1 million CPRIT Product Development Research Award to Hummingbird in February 2019.

- Immatics announced on February 26 a collaboration with Roche to evaluate the safety and efficacy of IMA101, Immatics' autologous cell therapy, in combination with atezolizumab TECENTRIQ), in patients with solid cancers. MD Anderson will conduct the combination clinical trial beginning later this year, led by Dr. Apostolia Tsimberidou, Professor of Department of Investigational Cancer Therapeutics at MD Anderson.

  Immatics developed IMA101 as a personalized, multi-targeted investigational immunotherapy for the treatment of multiple advanced metastatic solid tumors. The therapy is based on Immatics' ACTolog approach, which follows a technique pioneered by Cassian Yee, M.D., a CPRIT Scholar and Professor of Melanoma Medical Oncology at The University of Texas MD Anderson Cancer Center. ACTolog process allows us to utilize a

patient's own T cells to generate a targeted approach for treating solid tumors with increased safety and efficacy potential. CPRIT approved a $19.7 million CPRIT Product Development Research Award to Immatics US Inc. in February 2015 to support the development and clinical trials of ACTolog IMA101.

- The University of Texas MD Anderson Cancer Center appointed Dr. Giulio Draetta as its first Chief Scientific Officer, a role that champions innovation, develops strong partnerships, and provides focused leadership on the science and clinical translation of research programs. Dr. Draetta, a two-time CPRIT grantee, joined MD Anderson in 2011 from the Dana-Farber/Harvard Cancer Institute where he was a Presidential Scholar and deputy director of the Belfer Institute for Applied Cancer Science.

- First News at Four on KBTX in Bryan-College Station, featured Dr. Jason McKnight, faculty physician at the Texas A&M Physicians Family Medicine Center, and his CPRIT cancer prevention project, *Texas C-STEP*, as part of its feature on colorectal cancer month in March. *Texas C-Step* offers free colorectal cancer screenings to low-income residents in the Brazos Valley. Nearly 900 colonoscopies were performed through the project, with a 27% cancer precursor detection rate and 10 cases of cancer detected; 54 family medicine resident physicians received colonoscopy training as well.

- *UH News* featured *Taking Texas Tobacco Free*, Dr. Lorraine Reitzel's CPRIT project at the University of Houston, in February. Dr. Reitzel's program is reducing the incidence of tobacco-related cancers by assisting community behavioral health centers to adopt and implement comprehensive tobacco-free campus policies. During the first year of this project, seven substance use disorder treatment centers signed on to participate; multiple other centers are in various stages of program implementation. Dr. Reitzel is also the project director of a CPRIT award to disseminate the *Taking Texas Tobacco Free* program across the state.

- Dr. Michael Pignone's colorectal cancer screening project at The University of Texas at Austin Dell Medical School has doubled the percentage of CommUnityCare Health Center patients screened for colorectal cancer from 18.4% to 37% in just one year. This initiative was the focus of a news article in *UT News* in February.

- An article published in *UT Health News* for cervical cancer awareness month featured an interview with Dr. Paula Cuccaro of the University of Texas Health Science Center San Antonio about her CPRIT-funded *All for Them HPV* vaccination project. The project recruited 28 Houston Independent School District middle schools to participate in the first year of this project and conducted mobile vaccination clinics at 21 schools.

- CPRIT prevention grantee Dr. Allison Grimes addresses the issue of protecting pediatric cancer survivors from HPV-related second cancers in the *San Antonio MD News*. CPRIT's Oversight Committee awarded Dr. Grimes' project at The University of Texas Health Science Center at San Antonio a CPRIT prevention grant in August 2018. In addition to Dr. Grimes' work, the article highlights several other CPRIT awards.

Notable CPRIT Supported Accomplishments

- Dr. Abbey Berenson with The University of Texas Medical Branch at Galveston spoke at Emory University in Atlanta in February about her extraordinarily successful CPRIT cancer prevention projects on overcoming barriers to HPV vaccination. Dr. Berenson's HPV vaccination project in pediatric clinics achieved an impressive 99% series completion rate, well surpassing national averages. An oncologist in the audience at Dr. Berenson's presentation exclaimed he wanted to move to Texas because of the great work being done in the state.

- CPRIT Scholar Dr. Chonghui Cheng, associate professor at Baylor College of Medicine, has identified how some breast cancer cells can change, making them resistant to treatment. Her research, published in the journal *Genes & Development*, found that breast cancer cells can shift between two different forms of the cell surface protein CD44. Breast cancer cells expressing CD44s have increased metastatic behavior and resistance to therapy, while those expressing CD44v do not associate with these more dangerous behaviors. Alternative splicing, a process during gene expression that results in a single gene coding for multiple proteins, is the mechanism that allows these breast cancer cells to switch between the different CD44 proteins. The researchers envision that by manipulating the levels of the two forms of CD44, it might be possible to change the cancer cell properties in ways that may enhance the cancer's susceptibility to treatment.

- CPRIT-funded research at The University of Texas Southwestern Medical Center found that a combination of drugs – one targeting epidermal growth factor receptor (EGFR) and one targeting tumor necrosis factor (TNF) – effectively blocks the cancer from using TNF as an escape route from the targeting of EGFR. Using a mouse model, Dr. Amyn Habib, associate professor of Neurology and Neurotherapeutics, also showed that blocking TNF sensitizes the cancer to EGFR treatment. Based on these findings, reported in the *Journal of Clinical Investigation*, UT Southwestern researchers are planning a clinical trial of a two-drug strategy targeting both EGFR and TNF in lung cancer patients and those with glioblastomas; because the two drugs are already FDA-approved, they hope to be able to launch the trial within this year.

- A CPRIT-funded research program (RP170722 *Identification of Critical Dependencies and Actionable Therapeutic Options in Smarcb1-Deficient Pediatric Tumors*) led by Dr. Giulio Draetta, Chief Scientific Officer at MD Anderson, discovered that malignant rhabdoid tumors, a rare pediatric cancer without effective treatments, are sensitive to drugs that block the cancer cell's ability to dispose of misfolded proteins. The findings provide a much-needed therapeutic target for these and other cancers caused by mutations in the SMARCB gene. Based on these findings, published in *Cancer Cell*, the researchers are leading a clinical trial to test this approach in renal medullary carcinoma (RMC), a related adolescent cancer also characterized by SMARCB1 mutations.

- Dr. Zhijian "James" Chen, Professor in UT Southwestern's Department of Molecular Biology and CPRIT First Time Tenure Track Scholar Dr. Xiaochen Bai reported in two

papers published in *Nature* on key discoveries made regarding the structure of the STING protein. The STING protein is a key member of an important pathway in innate immunity, the body's first line of defense against foreign invaders and a potential target for a new generation of cancer immunotherapies.

The CPRIT-funded scientists made their discovery using UT Southwestern's new cryo-electron microscopy resource. Understanding the causes of cancer and identifying cancer treatments require knowledge of the cellular machineries (protein complexes) that are the drivers of tumor initiation, progression, and metastasis. Determining the three-dimensional structures of these machineries is essential to understanding the mechanisms of cancer, identifying drug targets, and developing therapeutics. Recent revolutionary advances have rendered cryo-electron microscopy the method of choice for determining protein structures in detail, i.e. at the level of individual atoms; while cryo-electron tomography enables researchers to view these molecular machines inside cells.

UT Southwestern invested $17 million to acquire and house a collection of instruments capable of performing cryo-electron microscopy that is unique in the United States. A CPRIT Core Facility grant helped to advance the facility, making these powerful resources widely available to the cancer research community. Dr. Chen and Dr. Bai's work is one example of the impact that investments in critical infrastructure like the CPRIT cryo-electron microscopy facility is making on accelerating cancer research in Texas.

- CPRIT Scholar Natalia Krienko Ph.D., assistant professor of Biosciences at Rice University, uses roundworms as a model system to identify conditions that can trigger cancer cell death while minimizing toxicity to normal cells and to look for new drugs that may be better at activating these pathways. In research reported in *PLOS Genetics* she found how a B12-deficient diet harms worms' health by reducing the worms' ability to metabolize branched-chain amino acids. The reduced ability to break down branched-chain amino acids leads to a buildup of toxic byproducts that damage mitochondria –known as the "powerhouse of the cell" and necessary to sustain life and support growth. Dr. Krienko's research on the effects of a B12-deficient diet identifies a potential new target to attack cancer cells.

- Research led by CPRIT Scholar Dr. Joshua Mendell, professor of Molecular Biology at UT Southwestern, has identified a genetic pathway that prevents premature aging in a mouse model. Published in *eLife*, the study examined the role of NORAD, a gene that Dr. Mendell discovered in 2015 that is important in maintaining the correct number of chromosomes in human cells as they divide. With their previous work limited to human cells grown in the laboratory, the researchers examined the role of NORAD in a living animal to better understand the gene's function in mammalian physiology. Like their laboratory findings in human cells, the researchers found that the loss of NORAD caused chromosomal defects in mice. But there were also some unexpected changes to mitochondria, the energy powerhouses of the cell. When the scientists removed NORAD, mitochondrial function became significantly abnormal. The mice also appeared to age rapidly. If disruption of NORAD is part of the aging process as this research finding suggests, then it will be

important to understand the mechanisms through which the disruption occurs. Eventually, this research could lead to an ability to prevent or reverse the aging process.

Personnel

CPRIT has filled all 35 of our full-time equivalent (FTE) positions.

CPRIT Outreach

- Chief Product Development Officer Dr. Cindy WalkerPeach presented "CPRIT: Investment, Infrastructure and Opportunities" on March 7 to the 1st Annual Regenerative Medicine Conference, hosted by the Medical Innovation Collaborative on the Texas Christian University campus.

- I presented "CPRIT and Innovation" at the American Cancer Society Cancer Action Network's legislative staff briefing held March 11 at the Texas Capitol.

- On March 11 Dr. WalkerPeach and Senior Program Manager for Product Development Rosemary French attended the Central Texas Health Innovation Social hosted by Capital City Innovation in Austin.

- Chief Prevention Officer Dr. Becky Garcia, Chief Scientific Officer Dr. Jim Willson, Sr. Program Manager for Academic Research Dr. Patty Moore and Sr. Program Manager for Prevention Ramona Magid met with Dr. Ruben Mesa, Director of the Mays Cancer Center at The University of Texas Health Science Center San Antonio on March 13 to learn more about the cancer center and to discuss grant opportunities.

86th Legislative Session

Legislation Affecting CPRIT

As of March 29, legislators have filed ten bills directly affecting CPRIT. The deadline for filing non-emergency bills has passed, so I do not expect additional CPRIT bills.

- House Bill 1 (Zerwas) - the House's General Appropriations Bill. As introduced, HB 1 included a $164 million appropriation from the Economic Stabilization Fund (aka the "Rainy Day" fund) to address CPRIT's exceptional item request for the fiscal biennium 2020-2021. The Committee Substitute HB 1 approved by the House on March 27 included all CPRIT's initial budget requests except for restoring CPRIT's transferability authorization.

- Senate Bill 1 (Nelson) – As introduced, the Senate's General Appropriations Bill does not include funding for CPRIT's exceptional item request.

- *House Joint Resolution 12* (Zerwas) – Authorizes submitting a second $3 billion in General Obligation Bonds for cancer research and prevention to voters at the November 5, 2019,

general election. The House Committee on Public Health is scheduled to hold a hearing on the bill April 3

- *House Bill 39* (Zerwas) and *Senate Bill 438* (Nelson) – Removes the restriction against new grant awards in FY 2023 if general obligation bonds are authorized by voters or another funding source is used for FY 2023 and beyond. The House Committee on Public Health is scheduled to hold a hearing on HB 39 April 3. SB 438 has been referred to the Senate Committee on Health and Human Services. A hearing is pending.

- *House Bill 1680* (Paddie) and *Senate Bill 619* (Birdwell) – Moves CPRIT's sunset review from FY 2023 to FY 2021. HB 1680 was referred to the House Committee on State Affairs and left pending on March 13. SB 619 was referred to the Senate Committee on Natural Resources and Economic Development. A hearing is pending.

- *House Bill 2570* (Zerwas) - Extends the period during which CPRIT can use any non-bond grant appropriations from three years to eight years. HB 2570 was referred to the House Committee on Appropriations.

- *House Bill 3147* (Parker) - Establishes a cancer clinical trial participation program. Although the bill does not reference CPRIT as introduced, a committee substitute is expected to place the program with CPRIT. Referred to the House Committee on Public Health.

- *Senate Bill 200* (Schwertner) – Requires CPRIT to develop a plan for self-sufficiency once the 2007 general obligation bond authorization expires. SB 200 was referred to the Senate Committee on Health and Human Services.

- *Senate Bill 2014* (Fallon) - authorizes voluntary contributions for pediatric cancer research when applying for a motor vehicle title; registering or renewing a motor vehicle; applying for a specialty license plate; and applying or renewing a driver's license or personal identification certificate. SB 2014 was referred to the Senate Committee on Transportation.

- *Senate Bill 2015* (Fallon) - establishes a pediatric cancer research license plate, "Kids Shouldn't Have Cancer." Fees raised from the license plate sales will be deposited in CPRIT's account and available to fund pediatric cancer research. SB 2015 was referred the Senate Committee on Transportation.

Committee Hearings and Action

- As previously reported, Chief Operating Officer Heidi McConnell and I presented CPRIT's budget request to the Senate Committee on Finance (SFC), chaired by Senator Jane Nelson, on January 23. The SFC met on March 28 and did not include CPRIT's exceptional item funding request in the Committee Substitute SB 1 (CSSB 1). The SFC did approve 1 FTE for information technology security and a technical adjustment to our line item amounts. I expect the full Senate to vote on CSSB 1 sometime in early April.

- Ms. McConnell and I presented CPRIT's budget request to the House Committee on Appropriations (HAC) Subcommittee on Articles I, IV and V on February 13. On March 4 HAC adopted all CPRIT's initial budget requests in its Committee Substitute for HB 1 (CSHB 1) except for restoring CPRIT's transferability authorization. This request is pending in Article XI for consideration by the conference committee in late April or early May.

- On March 13 I testified to the House Committee on State Affairs on House Bill 1680 that would revert CPRIT's Sunset Review year from 2023 to 2021. As of this writing the Committee has left the bill pending.

Looking ahead, the Speaker and Lt. Governor will appoint a conference committee to negotiate the considerable differences between the CSHB 1 and CSSB 1. The House and Senate will consider the resulting compromise budget bill, with a final vote likely in late May. If the final budget adopted by the House and Senate includes the $164 million appropriation for CPRIT's exceptional item request, we will award grants in fiscal years 2020 and 2021 at the same level ($280 million annually) as CPRIT has done for the past several years.

Legislative Outreach

I briefed the following members and/or members' staff on CPRIT's operations and legislative issues set for consideration by the 86th Texas Legislature:

- Representative Gina Hinojosa (February 1)
- Representative John Turner (February 6)
- Representative James Frank (February 6)
- Representative Reggie Smith (February 6)
- Representative Steve Allison (February 7)
- Senator Pat Fallon (February 12)
- Staff of Representative John Zerwas, with Ms. Doyle and Ms. McConnell (February 25)
- Staff of Senator Jane Nelson, with Ms. Doyle and Ms. McConnell (February 28)
- Staff of Representative Ben Leman (March 5)
- Staff of Representative Tan Parker, with Ms. Doyle and Ms. McConnell (March 20)

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT's grant management system (CGMS) produces a summary of delinquent reports each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 560+ grants that are either active or wrapping up grant activities and receives an average of 560 grantee reports each month.

As of March 20, five entities had not filed 23 Academic Research reports, two Product Development Research reports, and two Prevention reports. CPRIT's Grant Accountants and Compliance Specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the

required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT's Compliance Specialists performed 266 second-level reviews of grantee Financial Status Reports (FSRs) during the months of February and March. Eighteen FSRs (7%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the Compliance Specialists for final review and disposition.

Single Audit Tracking

Compliance Specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $750,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee submits the independent audit report with audit findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, there is one grantee with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approves the request. Compliance Specialists are working with the grantee to submit the audit.

Desk Reviews

Compliance Specialists performed 66 desk-based financial monitoring reviews during the months of February and March. Desk reviews verify that grantees expend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance Specialists are working with six grantees to remediate desk review findings.

On-Site Reviews

Compliance Specialists conducted three on-site reviews during February and March. On-site reviews examine the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance Specialists are working with two grantees to remediate on-site review findings.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual Attestation Form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Compliance Specialists to proactively work with grantees towards full compliance prior to a desk review or

on-site review. As of March 20, Compliance staff are working with three grantees who require additional corrective action related to their Attestations.

Training and Support

CPRIT staff conducted the first series of Annual Compliance Training webinars on March 6-7. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings cover grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This is the first training series offered this year in support of the annual compliance training requirement, which requires the Authorized Signing Official (ASO) and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

CPRIT staff also conducted a new grantee training webinar on February 4 for Magnolia Tejas (formerly Korysso Therapeutics, Inc.). The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new grantees to complete an initial compliance training program prior to receiving disbursement of Grant Award funds.

Academic Research Program Update

FY 2019 Cycle 2 Academic Research RFAs

CPRIT released the requests for applications (RFAs) for the second award cycle of FY 2019 (19.2) in August 2018. Applicants submitted 161 proposals to CPRIT for five different grant mechanisms by the January 30 deadline. Peer review will take place May 20 - May 24 in Dallas. Dr. Willson will present the Scientific Review Committee's (SRC) award recommendations to the Program Integration Committee (PIC) and the Oversight Committee in August.

Funding Mechanism	Applications Received	Funding Requested
Core Facilities Support Awards	19	$96,666,954
High Impact/High Risk Research Awards	97	$19,379,981
Early Translational Research Awards	28	$47,527,689
Collaborative Action Program to Reduce Liver Cancer Mortality in Texas: Collaborative Action Center Award	2	$5,999,901
Collaborative Action Program to Reduce Liver Cancer Mortality in Texas: Investigator Initiated Research Awards	15	$36,556,484
TOTAL	**161**	**$206,131,009**

Recruitment Applications

CPRIT received 14 recruitment applications for the third quarter of FY 2019. The SRC reviewed applications for these cycles on February 13 and March 14. Dr. Willson will present the SRC's four award recommendations to the PIC and the Oversight Committee at the Oversight Committee meeting May 15.

Mechanism	Received	Funds Requested	Approved by SRC	Funds
Recruitment Established Investigators	2	$12,000,000	1	$6,000,000
Recruitment of Rising Stars	7	$26,562,426	2	$7,562,426
Recruitment of First-Time, Tenure Track Faculty Members	5	$10,000,000	1	$2,000,000
TOTAL	**14**	**$48,562,426**	**4**	**$15,562,426**

FY 2020 Cycle 1 (20.1) RFAs

CPRIT released the FY2020 Cycle 1 RFAs (described below) on January 10, 2019. Applications are due on June 5, 2019. CPRIT has scheduled peer review October 17- 24 in Dallas. Dr. Willson will present the SRC's recommendations to PIC and the Oversight Committee in February 2020.

- *Individual Investigator Research Awards (IIRA)*
  Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications accepted.
  Award: Up to $300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- *Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)*
  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.
  Award: Up to $300,000 per year. Applicants that plan to conduct a clinical trial as part of the project may request up to $500,000 in total costs. Exceptions permitted if extremely well justified; maximum duration: 4 years.

- *Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)*
  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, early-stage progression, and/or early detection of cancer. Research may be laboratory-, clinical-, or population- based, and may include behavioral/intervention, dissemination, or health services/outcomes research to reduce cancer incidence or promote early detection. Competitive renewal applications accepted.
  Award: Up to of $300,000 per year for laboratory and clinical research; up to $500,000 per year for population-based research. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- *Individual Investigator Research Awards for Clinical Translation (IIRACT)*
  Supports applications which propose innovative clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial or involve analyses of biospecimens from patients enrolled on a completed trial for which the outcomes are known. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices.
  Award: Up to $400,000 per year. Maximum duration: 3 years. Applicants that plan to conduct a clinical trial as part of the project may request up to $600,000 in total costs and a maximum duration of 4 years. Exceptions permitted if extremely well justified.

Product Development Research Program Update

Product Development Research Applications FY 2019 Cycle 1

During the Due Diligence Evaluation phase of the FY 2019 Cycle 1 review, the CPRIT Product Development Review Council (PDRC) took no action on two applications pending review of additional information requested from each applicant. If the PDRC decides to recommend awards to either of the two companies after reviewing the additional information, Dr. WalkerPeach will bring the recommendations to the PIC and the Oversight Committee for consideration at the May or August meetings.

Product Development Research Applications FY 2019 Cycle 2

CPRIT released three RFAs for the FY 2019 Cycle 2 (19.2) cycle on December 5, 2018, and accepted applications through January 30. Companies submitted 27 proposals, which CPRIT assigned to peer reviewers for evaluation. The peer review panels met on March 18 and 19 to discuss the applications and determine the companies to invite to make in-person presentations to the peer review panels at meetings CPRIT will hold in Dallas April 16-18. The panels selected 11 companies to move forward to the in-person review stage.

Mechanism	Applications Received	Funds Requested	In-Person Presentations	Funds Requested
Texas Company	4	$63.9 million	3	$45.9 million
Relocation Company	9	$108.8 million	3	$23.0 million
Seed Company	14	$37.8 million	5	$15.0 million
TOTAL	**27**	**$210.5 million**	**11**	**$83.9 million**

Applicants that score well enough following the in-person presentations will move forward to the due diligence phase of review. The PDRC will convene in July to consider the due diligence reports and make final award recommendations for consideration by the PIC and the Oversight Committee. Dr. WalkerPeach will present the PIC's recommendations for the 19.2 cycle awards at the August 2019 Oversight Committee meeting.

Product Development Research FY 2020 Cycle 1

The application portal for the FY 2020 Product Development Research award cycle (20.1) will open in June and accept applications through early August. Dr. WalkerPeach will present the PIC award recommendations for the 20.1 cycle to the Oversight Committee at the February 2020 meeting. Unless the legislature approves additional funding during the current session, CPRIT's Product Development Research Program will release only one cycle of RFAs for product development grants in FY 2020. If CPRIT secures additional funding, the Product Development Research Program is positioned to release a second cycle of RFAs for FY 2020.

The Oversight Committee approved the following three RFAs for the 20.1 cycle at its meeting in February:

- *Texas Company Product Development Research Award*
  Supports early-stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must headquarter in Texas.
  Award: Maximum amount $20 million over 36 months

- *Relocation Company Research Award*
  Supports early-stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a

robust industry; or must fill a treatment or research gap. Companies must relocate to Texas upon receipt of award.
Award: Maximum amount $20 million over 36 months

- *Seed Award for Product Development Research*
  Supports projects that are earlier in their development timeline than CPRIT's two other Product Development Awards, the Texas Company Award, and the Company Relocation Award. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Company applicants must headquarter in Texas or be willing to relocate to Texas upon receipt of award. Award: Maximum amount of $3 million over 36 months.

Product Development Research Program Outreach to CPRIT Portfolio Companies

As part of familiarizing herself with the CPRIT company portfolio, Dr. WalkerPeach is traveling around Texas over the next several months to meet company representatives at their headquarters and laboratories to learn about their CPRIT-funded projects. She kicked off this initiative in early March with a trip to the Dallas/Fort Worth metroplex to visit three CPRIT grantee companies: OncoNano Medicine, Nexeon MedSystems, and Peloton Therapeutics. Senior Product Development Research Program Manager Rosemary French accompanied Dr. WalkerPeach to Houston March 26 – 28 to meet with several of the 17 CPRIT grantee companies based in or around the city.

Prevention Program Update

FY 2019 Cycle 2 (19.2) Prevention Applications

CPRIT released FY 2019 Cycle 2 RFAs in November 2018. Applicants submitted 27 proposals requesting $38.1 million (see table below) by the February 20 deadline. Peer review will take place May 22-23 in Dallas. The Prevention Review Council's recommendations will be presented to the PIC and the Oversight Committee in August 2019.

Mechanism	Received	Funds Requested
Evidence-based Cancer Prevention Services	7	$ 6,844,590
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	13	$24,422,409
Tobacco Control and Lung Cancer Screening	7	$ 6,838,830
TOTAL	**27**	**$38,105,829**

FY 2020 Cycle 1 (20.1) Prevention RFAs

CPRIT will release four RFAs (described below) in May for the first review cycle of FY 2020. The application deadline is September 4.

FY 2020 Cycle 1 Prevention RFAs

- *Evidence-Based Cancer Prevention Services*
  Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.
  Award: Maximum of $1 million over 36 months.

- *Tobacco Control and Lung Cancer Screening*
  Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
  Award: Maximum of $1 million over 36 months.

- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
  Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
  Award: Maximum of $2 million over 36 months.

- *Dissemination of CPRIT-Funded Cancer Control Interventions*
  Seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
  Award: Maximum of $300,000 over 24 months.

Advisory Committees

- The University Advisory Committee met in Houston on February 25.

- The Advisory Committee on Childhood Cancers met by teleconference on March 27.

The Clinical Trials Advisory Committee, the University Advisory Committee, and the Product Development Advisory Committee will present their annual reports to the Oversight Committee at its May 15 meeting.

Communications Update

Cancer Awareness Events

- In recognition of National Cancer Prevention Month in February, CPRIT posted a video featuring interviews of prominent CPRIT prevention grantees on the Prevention Program's landing page and distributed via social media. CPRIT posted other prevention-related social media during February including prevention information on World Cancer Day (February 4) from the American Association of Cancer Researchers and highlighted various CPRIT grantee prevention program activities.

- For Colorectal Cancer Awareness month in March, Dr. Willson and a colorectal cancer survivor discuss CPRIT's prevention and research initiatives in a new video. CPRIT also posted information from Cancer.Net, Anal Cancer Foundation, and the CDC, as well as sharing several social media mentions and various CPRIT grantee prevention program activities.

Special Events

- Senior Communications Specialist Chris Cutrone is working with Representative Rose's office on events to commemorate Minority Cancer Awareness Day on April 4, including coordinating with the UT Austin Dell Medical School and Moncrief Cancer Center for potential panel discussion participants.

- CPRIT continues releasing a series of grantee profiles for social media designed to drive visitors to the CPRIT Scholars section of the website. The new website design allows CPRIT to enhance its storytelling capabilities with a multi-channel platform for posting, curating, and distributing CPRIT and related content.

- CPRIT is evaluating proposals for hotel and conference venues for the *2020 CPRIT Innovations VI Conference*. CPRIT will present the staff's choice for the venue proposal to the Oversight Committee at the May 15 meeting.

Other activities

- Mr. Cutrone worked with a reporter from *The Cancer Letter* for an article released March 22. The Cancer Letter article includes an interview with Dr. Willson.

- The communications staff interviewed Dr. Stephen Skapek of The University of Texas Southwestern Medical Center after his presentation to the Oversight Committee on February 21. CPRIT will feature Dr. Skapek's interview in a video on CPRIT-funded childhood cancer projects.

Social media

Facebook (last 28 days):
- Reach: 1,305
- Engagement: 370
- Most popular post: Innovation in the State's Capital: Watch this video on the revolutionary MasSpec Pen, created by Dr. Livia Eberlin of the College of Natural Sciences at The University of Texas at Austin. #CPRITImpact #MasSpecPen.

Twitter (February):
- 21,900 impressions
- Top tweet: CPRIT-funded preclinical study at @MDAndersonNews identifies vulnerability in orphan cancers with SMARCB1 mutations, spurs launch of Phase II clinical trial: https://cprit.us/2N3QZUC.

Twitter (March 1-19):
- 5,100 impressions
- Top tweet: It's official—Dr. Julian West will join the @RiceUniversity Department of Chemistry July 1 thanks to a $2 million CPRIT Scholar grant: https://cprit.us/2EBFL5W.

Operations, Audit and Finance Update

I am representing CPRIT on a Texas Facilities Commission ad hoc working group of Travis Building tenants to address specific concerns, including:

- Improving signage directing pedestrian traffic through the two construction zones surrounding the Travis Building;
- Employee and visitor parking shortage;
- Security; and
- Maintenance and cleanliness.

We have had two meetings with more to follow. Signage has improved as has some maintenance and cleanliness issues.

Subcommittee Meetings

Listed below are the regularly scheduled subcommittees in advance of the May 15 Oversight Committee meeting.

Because of the 2019 legislative session, CPRIT will hold **the May 15 Oversight Committee meeting at the Texas Higher Education Coordinating Board, 1200 East Anderson Lane.**

Board Governance	May 2 at 10:00 a.m.
Audit	May 6 at 10:00 a.m.
Prevention	May 7 at 10:00 a.m.
Academic Research	May 8 at 10:00 a.m.
Product Development	May 9 at 10:00 a.m.
Nominations	May 10 at 10:30 a.m.

CPRIT will send an agenda, call-in information, and supporting material to the subcommittees one week prior to the meeting date.

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CPRIT has awarded **1,372** grants totaling **$2.260 billion**

- 216 prevention awards totaling $235.5 million
- 1,156 academic research and product development research awards totaling $2.025 billion

Of the $2.025 billion in academic research and product development research awards,

- 31.1% of the funding ($630.2 million) supports clinical research projects
- 25.2% of the funding ($510.2 million) supports translational research projects
- 26.3% of funding ($532.0 million) supports recruitment awards
- 14.4% of the funding ($292.7 million) supports discovery stage research projects
- 3.0% of funding ($59.9 million) supports training programs.

CPRIT has 8 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 4 Academic Research
- 1 Prevention

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE APRIL 2019
DATE:	MAY 1, 2019

Topics in this memo cover the month of April 2019 and include preparations for the upcoming Oversight Committee May 15 meeting, recent milestones in our fight against cancer, a staffing summary, CPRIT outreach efforts, legislative session activities, and updates from Compliance, Programs, and Operations.

Upcoming Oversight Committee Meeting

The Oversight Committee will meet May 15 at 10:00 a.m. in the board room at the Texas Higher Education Coordinating Board, 1200 E. Anderson Lane. Please note that this is a change from our regular location at the Capitol. We do not hold our meetings at the Capitol while the legislature is in session.

Currently, we have seven Oversight Committee members and do not expect new appointments before the May meeting. A quorum of five members is necessary to conduct official business. **Please notify me as soon as possible if you are unable to attend the May meeting or have travel arrangements that will cause you to arrive late or leave before 2:00.**

You will receive an email from CPRIT by May 3 with a link and password to access the Program Integration Committee's award recommendations via the grant award portal. The portal has a summary of each award slate and supporting documentation on each project proposed for an award. You will be considering several proposed CPRIT recruitment awards. Please allow time to complete the individual conflict of interest checks and review the supporting material.

CPRIT will post the final agenda for the Oversight Committee meeting by May 7; I have attached a tentative agenda. Oversight Committee members will receive an electronic copy of the agenda packet by May 8. Hard copies of the agenda packet will be available at the meeting.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- The Texas Tech University Health Sciences Center *Daily Dose* featured Dr. Rakhshanda Rahman's CPRIT project, Access to Breast and Cervical Care for West Texas, on April 11.

This project, with additional expansion funding, has educated more than 26,800 women, provided more than 9,500 breast and cervical screening and diagnostic services and detected 123 precursors and cancers since 2010.

- Kathryn Pratt, BSN, RN, OCN, CBCN, Nurse Navigator in Cancer Genetics at The University of Texas Southwestern Medical Center, presented findings on the impact of a genetic patient navigator (GPN) at the Oncology Nursing Society 44th Annual Congress in Anaheim, CA. The CPRIT-funded project showed that introducing a GPN improved education on cancer risks, adherence to risk reduction behaviors, and genetic health literacy. In the first 24 months, the program held 62 public education services involving 578 people, and 436 people were navigated to 431 services across 24 counties. The program also offered professional education services to improve genetic literacy among providers; sixteen outreach events in 25 counties heightened the health literacy of 2,357 healthcare providers.

- The March 2019 edition of the *Texas Health Journal*, a publication of The University of Texas System, highlighted two CPRIT-funded Prevention projects. *All for Them*, a project run by Dr. Paula Cuccaro at The University of Texas Health Science Center at Houston focuses on increasing HPV vaccination rates among ethnic minority middle schoolers in medically underserved areas. *All for Them* is currently in 29 Houston-area schools, with overall participation numbers increasing year over year. Dr. Paul McGaha's colorectal cancer screening project at the University of Texas Health Science Center at Tyler has screened thousands of uninsured people in East Texas, the region in Texas with the highest death rates from colorectal cancer. Over the course of its work, 56 of the people screened exhibited precursors to colorectal cancer, and 14 more were diagnosed with cancer.

- Immatics US Inc. announced on April 9, 2019, that it initiated patient enrollment in a phase I trial of IMA203, the company's third T-cell receptor (TCR)-transduced adoptive cell therapy program. IMA203 is an investigational immunotherapy based on genetic engineering of the patient's own T cells to express an exogenous TCR. The goal is to redirect and activate T cells to treat solid tumors. Immatics received a $19.7 million CPRIT Product Development award in February 2015.

- On April 30 Medicenna Therapeutics announced it has completed enrolment of the Phase 2b clinical study of its lead compound, MDNA55, for the treatment of recurrent glioblastoma, the most common and uniformly fatal form of brain cancer. Medicenna, a CPRIT grantee, is a clinical stage immunotherapy company developing treatments for brain cancers affecting adults and children. The company's novel Interleukin-4 Empowered Cytokines fuse to cell-killing payloads and act as molecular Trojan horses targeting tumors that over-express the IL-4 receptor (IL4R). The company is evaluating data from 25 patients with recurrent glioblastoma treated at the high dose and assessing the impact of IL4R expression on survival outcomes as well as tumor response.

  In the Phase 2b open-label study in up to 52 patients with glioblastoma at first or second relapse, investigators administered MDNA55 only once directly into the brain tumor using a technique known as Convection Enhanced Delivery. The technique allows precision delivery

of MDNA55 directly into the tumor tissue and the surrounding healthy brain containing infiltrative tumor cells, while avoiding exposure to the rest of the body.

To date clinicians treated more than 130 patients with MDNA55 in multiple clinical trials, including more than 110 patients with rGBM, building a significant safety profile, evidence of anti-tumor effect and mechanistic dataset. Medicenna expects multiple presentations of clinical results at relevant conferences this year and will provide updates following meetings with regulatory agencies regarding the future path to commercialization of MDNA55. Medicenna received a $14 million Product Development Award in February 2015 to support the clinical trials.

- The American Association for Cancer Research (AACR) recognized CPRIT Scholar and Nobel Laurette Jim Allison for his contribution to the emergence of immune-oncology as a major therapeutic strategy for cancer during the opening ceremony of the 2019 AACR meeting. A major symposium at the AACR meeting further highlighted Dr. Allison's contribution and impact, tracing the development of the immune checkpoint inhibitor, CTLA-4, from basic discovery to a cure for patients with advanced melanoma and subsequent development of additional highly effective immune-oncology therapies and prospects for additional cures.

- CPRIT grantee Dr. Pam Sharma, co-leader of the Parker Institute for Cancer Immunotherapy at The University of Texas M.D. Anderson Cancer Center, chaired a major symposium at the AACR meeting where she described a series of innovative clinical trials underway at MD Anderson that have extended the impact of immune-oncology therapy to pancreatic cancer, brain cancer, bladder and prostate cancer, and triple negative breast cancers. To date over 3,500 MD Anderson patients have entered these trials.

- Baylor College of Medicine investigators reported on a major treatment breakthrough for childhood and adult osteosarcoma at the AACR annual meeting. Significant clinical responses occurred in 5 of 10 patients treated with their own blood cells that had been genetically modified to recognize their cancer. One of the first CPRIT MIRA grants awarded in 2010 supported the development of this immune cell therapy for osteogenic sarcoma. Most exciting was the report that one teenage patient with metastatic osteosarcoma treated on the trial had a complete resolution of her disease that has now continued for 32 months.

- CPRIT Scholar Dr. Jihye Yun, Assistant Professor of Molecular and Human Genetics at Baylor College of Medicine, published a study in *Science* that implicates fructose, the sugar in corn syrup, in the development of colon cancer. While current thought is that sugar is harmful to human health mainly because consuming too much can lead to obesity, Dr. Yun's study showed that consuming a daily modest amount of fructose - the equivalent of drinking about 12 ounces of a sugar-sweetened beverage daily - accelerates the growth of intestinal tumors in mouse models of colon cancer, independent of obesity. The team also discovered the mechanism by which the consumption of sugary drinks can directly feed cancer growth, suggesting potential novel therapeutic strategies.

- The American Society of Clinical Investigators (ASCI) voted to extend membership to CPRIT Scholar Dr. Hal Zhu, Associate Professor of Internal Medicine at The University of Texas Southwestern Medical Center. The ASCI membership includes physician-scientists under the age of 50 from all medical specialties selected for their outstanding records of scholarly achievement in biomedical research.

Personnel

CPRIT has filled all 35 of our full-time equivalent (FTE) positions.

Dr. Becky Garcia, CPRIT's Chief Prevention and Communications Officer, announced that she will retire, effective May 31. Dr. Garcia created CPRIT's prevention program. In the ten years that she has served as CPRIT's Chief Prevention and Communications Officer, the prevention program has awarded more than 200 prevention awards totaling $235.5 million. The CPRIT prevention projects have affected Texans in all 254 counties, providing more than 5.2 million cancer prevention services. Ramona Magid, currently the Sr. Prevention Program Manager, has agreed to become the Chief Prevention Officer upon Dr. Garcia's retirement.

CPRIT Outreach

- On March 29 Chief Product Development Officer Dr. Cindy WalkerPeach delivered an overview of CPRIT to a delegation of State of Arkansas, City and University officials and Arkansas for-profit and not-for-profit organizations, including the Walton Family Foundation. IC2 Institute at The University of Texas at Austin hosted the event.
- Chief Prevention Officer Dr. Becky Garcia attended the Texas Health Improvement Network meeting on April 17 as an Advisory Council member.

- Dr. Garcia participated on a Cancer Screening and Prevention panel at the Texas Association of Community Health Centers 2019 Clinical Conference on April 26.

86th Legislative Session

Confirmation of Oversight Committee Member

On April 25 the Senate Committee on Nominations recommended Senate confirmation of Dr. David A. Cummings to the Oversight Committee, the full Senate subsequently approved the appointment on May 1. Dr. Cummings' appointed term is for the period of August 27, 2018 through January 31, 2023. Gubernatorial appointments to the Oversight Committee require Senate confirmation; Speaker and Lieutenant Governor appointments do not.

Legislation Affecting CPRIT

As of April 30, legislators have filed twelve bills directly affecting CPRIT. The deadline for filing non-emergency bills has passed, so I do not expect additional CPRIT bills.

- *House Bill 1* (Zerwas) - the House's General Appropriations Bill. As introduced, HB 1 included a $164 million appropriation from the Economic Stabilization Fund (aka the "Rainy Day" fund) to address CPRIT's exceptional item request for the fiscal biennium 2020-2021. The Committee Substitute HB 1 approved by the House on March 27 included all CPRIT's initial budget requests except for restoring CPRIT's transferability authorization.

- *Senate Bill 1* (Nelson) – As introduced, the Senate's draft budget bill did not include funding for CPRIT's exceptional item request. The Senate Committee on Finance substituted its draft budget for HB 1. What is now the Senate Committee Substitute for HB 1 does not include CPRIT's exceptional item funding request but does include one FTE for information technology security, a technical adjustment to our line item amounts, and a technical adjustment to CPRIT's unexpended balance rider to clarify the use of unexpended bond funds during 2020-2021. The Senate approved the Committee Substitute on April 9.

The House and Senate each appointed five members to negotiate the considerable differences between their versions of HB 1. The Senate Conferees are: Nelson (chair), Huffman, Kolkhorst, Taylor, and Nichols. The House Conferees are: Zerwas (chair), Longoria, Walle, G. Bonnen, and S. Davis. The Conference Committee began meeting on April 23.

The Conference Committee Report will be voted on by both chambers in late May, probably the week of May 22. The session ends May 27. If the final budget includes the $164 million appropriation for CPRIT's exceptional item request, CPRIT will award grants in fiscal years 2020 and 2021 at the same level ($280 million annually) as we have done for the past several years.

- *House Joint Resolution 12* (Zerwas) – Authorizes submitting approval of a second $3 billion in General Obligation Bonds for cancer research and prevention to voters at the November 5, 2019, general election. The House engrossed (adopted) the resolution on April 17 by a vote of 130-16-2 and it has been received by the Senate.

- *House Bill 39* (Zerwas) and *Senate Bill 438* (Nelson) – Removes the restriction against new grant awards in FY 2023 if general obligation bonds are authorized by voters or another funding source is used for FY 2023 and beyond. The House engrossed (adopted) the bill on April 17 by a vote of 124-16-2 and it was received by the Senate and referred to the Committee on Administration. SB 438 was approved by the Senate Committee on Health and Human Services by a vote of 9-0. Since HB 39 was passed by the House, SB 438 was removed from the Senate Calendar and a hearing on HB 39 is scheduled at the Administration Committee on May 1.

- *House Bill 1680* (Paddie) and *Senate Bill 619* (Birdwell) – As introduced, both bills moved CPRIT's sunset review from FY 2023 to FY 2021. The House Committee on State Affairs held a hearing on HB 1680 on March 13 and left the bill pending. The Senate Committee on Natural Resources and Economic Development approved a committee substitute for SB 619 by a vote of 9-0. The Committee Report for SB 619 removes CPRIT from the bill, meaning

that our sunset date would remain August 31, 2023. SB 619 was engrossed (adopted) by the Senate on April 30 and received by the House on the same day.

- *House Bill 2570* (Zerwas) - Extends the period during which CPRIT can use any non-bond grant appropriations from three years to eight years. HB 2570 was engrossed (adopted) by the House on April 18 by a vote of 120-14-1 and it has been received by the Senate.

- *House Bill 3147* (Parker) - Establishes a cancer clinical trial participation program. Although the bill did not reference CPRIT as introduced, the committee substitute authorizes CPRIT to use grant funds to reimburse patient expenses associated with clinical trial participation, including transportation, lodging, travel, parking and tolls, and other costs considered appropriate. The House Committee on Public Health approved Committee Substitute HB 3147 on April 24 by a vote of 10-0. HB 3147 is currently in the House Committee on Calendars to be scheduled for the House calendar.

- *Senate Bill 200* (Schwertner) – Requires CPRIT to develop a plan for self-sufficiency once the 2007 general obligation bond authorization expires. SB 200 was referred to the Senate Committee on Health and Human Services.

- *Senate Bill 2014* (Fallon) - Authorizes voluntary contributions for pediatric cancer research when applying for a motor vehicle title; registering or renewing a motor vehicle; applying for a specialty license plate; and applying or renewing a driver's license or personal identification certificate. The Senate Committee on Transportation held a hearing on SB 2014 on April 10 and left the bill pending.

- *Senate Bill 2015* (Fallon) - Establishes a pediatric cancer research license plate, "Kids Shouldn't Have Cancer." Fees raised from the license plate sales will be deposited in CPRIT's account and available to fund pediatric cancer research. The Senate Committee on Transportation held a hearing on SB 2015 on April 10 and approved the Committee Report by a vote of 9-0. The Senate engrossed (adopted) SB 2015 by a unanimous vote on April 23. It was received by the House and referred to the House Committee on Transportation on April 29.

Committee Hearings and Action

- As previously reported, Representative Zerwas laid out HB 39 and HJR 12 to the House Committee on Public Health on April 3. Five witnesses testified in favor of the bills. The committee had an extensive agenda, so the advocates apparently worked with Rep. Zerwas' office to limit public testimony to five witnesses. An additional 36 individual and organizations registered in support of the legislation.

- On April 10, Senator Fallon presented SB 2014 and SB 2015 to the Senate Committee on Transportation. At Senator Fallon's request, Dr. Willson testified as a resource witness regarding the childhood cancer research that CPRIT has supported.

Legislative Outreach

I discussed CPRIT legislative issues with the following members and/or members' staff:

- Representative John Zerwas (April 2)
- Staff of Senator Jane Nelson (April 3)
- Staff of Representative Matt Schaeffer, with Chief Operating Officer Heidi McConnell (April 11)

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT's grant management system (CGMS) produces a summary of delinquent reports each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 560+ grants that are either active or wrapping up grant activities and receives an average of 560 grantee reports each month.

As of April 22, one entity has not filed eight Academic Research reports. CPRIT's grant accountants and Compliance Specialists review and process incoming reports and reach out to grantees to resolve filing issues. Typically, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT's Compliance Specialists performed 129 second-level reviews of grantee Financial Status Reports (FSRs) during the month of April. Fifteen FSRs (12%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the Compliance Specialists for final review and disposition.

Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $750,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee submits the independent audit report with audit findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, there is one grantee with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request. Compliance Specialists are working with the grantee to submit the audit.

Desk Reviews

Compliance Specialists performed 55 desk-based financial monitoring reviews during the month of April. Desk reviews verify that grantees expend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance Specialists are working with one grantee to remediate desk review findings.

On-Site Reviews

Compliance Specialists conducted one on-site review during April. On-site reviews examine the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance Specialists are working with one grantee to remediate on-site review findings.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual Attestation Form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Compliance Specialists to proactively work with grantees towards full compliance prior to a desk review or on-site review. As of April 24, Compliance staff are working with two grantees who require additional corrective action related to their attestation.

Training and Support

CPRIT staff conducted a new Authorized Signing Official (ASO) training webinar on April 24 for Centro San Vicente. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

Academic Research Program Update

FY 2019 Cycle 2 Academic Research RFAs

CPRIT released the requests for applications (RFAs) for the second award cycle of FY 2019 (19.2) in August 2018. Applicants submitted 161 proposals to CPRIT for five different grant mechanisms by the January 30 deadline. Peer review will take place May 20 - May 24 in Dallas. Dr. Willson will present the Scientific Review Committee's (SRC) award recommendations to the Program Integration Committee (PIC) and the Oversight Committee in August.

Funding Mechanism	Applications Received	Requested Funding
Core Facilities Support Awards	19	$96,666,954
High Impact/High Risk Research Awards	97	$19,379,981
Early Translational Research Awards	28	$47,527,689
Collaborative Action Program to Reduce Liver Cancer Mortality in Texas: Collaborative Action Center Award	2	$5,999,901
Collaborative Action Program to Reduce Liver Cancer Mortality in Texas: Investigator Initiated Research Awards	15	$36,556,484
TOTAL	**161**	**$206,131,009**

Recruitment Applications

CPRIT received 23 recruitment applications for the third quarter of FY 2019. The SRC reviewed applications for these cycles on February 13, March 14, and April 11. Dr. Willson will present the SRC's award recommendations to the PIC and the Oversight Committee in May.

Funding Mechanism	Received	Requested Funding	Approved by SRC	Requested Funding
Recruitment Established Investigators	3	$18,000,000	2	$12,000,000
Recruitment of Rising Stars	9	$26,562,426	2*	$7,562,426
Recruitment of First-Time, Tenure Track Faculty Members	11	$22,000,000	6	$2,000,000
TOTAL	**23**	**$66,562,426**	**10**	**$31,562,426**

* The SRC recommended three Rising Star awards, but the applicant subsequently withdrew the application prior to the PIC meeting.

FY 2020 Cycle 1 (20.1) RFAs

CPRIT released the FY2020 Cycle 1 RFAs (described below) on January 10. Applications are due on June 5. CPRIT has scheduled peer review October 17- 24 in Dallas. Dr. Willson will present the SRC's recommendations to the PIC and the Oversight Committee in February 2020.

- *Individual Investigator Research Awards (IIRA)*
  Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications accepted.

Award: Up to $300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- *Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)*
  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.
  Award: Up to $300,000 per year. Applicants that plan to conduct a clinical trial as part of the project may request up to $500,000 in total costs. Exceptions permitted if extremely well justified; maximum duration: 4 years.

- *Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)*
  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, early-stage progression, and/or early detection of cancer. Research may be laboratory-, clinical-, or population- based, and may include behavioral/intervention, dissemination, or health services/outcomes research to reduce cancer incidence or promote early detection. Competitive renewal applications accepted.
  Award: Up to of $300,000 per year for laboratory and clinical research; up to $500,000 per year for population-based research. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- *Individual Investigator Research Awards for Clinical Translation (IIRACT)*
  Supports applications which propose innovative clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial or involve analyses of biospecimens from patients enrolled on a completed trial for which the outcomes are known. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices.
  Award: Up to $400,000 per year. Maximum duration: 3 years. Applicants that plan to conduct a clinical trial as part of the project may request up to $600,000 in total costs and a maximum duration of 4 years. Exceptions permitted if extremely well justified.

Product Development Research Program Update

Product Development Research Applications FY 2019 Cycle 1

During the Due Diligence Evaluation phase of the FY 2019 Cycle 1 review, the CPRIT Product Development Review Council (PDRC) took no action on two applications pending review of additional information requested from each applicant. If the PDRC decides to recommend awards to either of the two companies after reviewing the additional information, Dr. WalkerPeach will present the recommendation(s) to the PIC and the Oversight Committee for consideration at the August meeting.

Product Development Research Applications FY 2019 Cycle 2

CPRIT released three RFAs for the FY 2019 Cycle 2 (19.2) cycle on December 5, 2018, and accepted applications through January 30. Companies submitted 27 proposals, which CPRIT assigned to peer reviewers for evaluation. The peer review panels met in March and selected 11 companies to make in-person presentations to the peer review panel in Dallas April 16-18. Following the in-person presentations, the peer review panels voted to conduct due diligence evaluation on four applicants. The PDRC will meet in July to consider the due diligence reports and make final award recommendations. Dr. WalkerPeach will present the PDRC's recommendations to the PIC and the Oversight Committee for consideration at the August meeting.

Mechanism	Applications Received	Funds Requested	In-Person Review	Funds Requested	Due Diligence	Funds Requested
Texas Company	4	$63.9M	3	$45.9M	1	$15.4M
Relocation Company	9	$108.8M	3	$23.0M	1	$7.4M
Seed Company	14	$37.8M	5	$15.0M	2	$6.0M
TOTAL	**27**	**$210.5M**	**11**	**$83.9M**	**4**	**$28.8M**

Product Development Research FY 2020 Cycle 1

The application portal for the FY 2020 Product Development Research award cycle (20.1) will open in June and accept applications through early August. Dr. WalkerPeach will present the PIC award recommendations for the 20.1 cycle to the Oversight Committee at the February 2020 meeting. Unless the legislature approves additional funding during the current session, CPRIT's Product Development Research Program will release only one cycle of RFAs for product development grants in FY 2020. If CPRIT secures additional funding, the Product Development Research Program is positioned to release a second cycle of RFAs for FY 2020.

The Oversight Committee approved the following three RFAs for the 20.1 cycle at its meeting in February:

- *Texas Company Product Development Research Award*
  Supports early-stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must headquarter in Texas.
  Award: Maximum amount $20 million over 36 months

- *Relocation Company Research Award*
  Supports early-stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must relocate to Texas upon receipt of award.
  Award: Maximum amount $20 million over 36 months

- *Seed Award for Product Development Research*
  Supports projects that are earlier in their development timeline than CPRIT's two other Product Development Awards, the Texas Company Award, and the Company Relocation Award. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Company applicants must headquarter in Texas or be willing to relocate to Texas upon receipt of award. Award: Maximum amount of $3 million over 36 months.

Product Development Research Program Outreach to CPRIT Portfolio Companies

As part of familiarizing herself with the CPRIT company portfolio, Dr. WalkerPeach is traveling around Texas over the next several months to meet company representatives at their headquarters and laboratories to learn about their CPRIT-funded projects. She kicked off this initiative in early March with a trip to the DFW metroplex to visit three CPRIT grantee companies. Senior Product Development Research Program Manager Rosemary French accompanied Dr. WalkerPeach to Houston March 26 – 28 to meet with nine of the 17 CPRIT grantee companies based in or around the city. While they were in Houston, Dr. WalkerPeach and Ms. French also met with Dr. Richard Gibbs, Director of the Human Genome Sequencing Center at Baylor College of Medicine, and Ann Tanabe, CEO of BioHouston.

Prevention Program Update

FY 2019 Cycle 2 (19.2) Prevention Applications

CPRIT released FY 2019 Cycle 2 RFAs in November 2018. Applicants submitted 27 proposals requesting $38.1 million (see table below) by the February 20 deadline. Peer review will take place May 22-23 in Dallas. The Prevention Review Council's recommendations will be presented to the PIC and the Oversight Committee in August 2019.

Mechanism	Received	Funds Requested
Evidence-based Cancer Prevention Services	7	$ 6,844,590
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	13	$24,422,409
Tobacco Control and Lung Cancer Screening	7	$ 6,838,830
TOTAL	**27**	**$38,105,829**

FY 2020 Cycle 1 (20.1) Prevention RFAs

CPRIT will release four RFAs (described below) in May for the first review cycle of FY 2020. The application deadline is September 4.

FY 2020 Cycle 1 Prevention RFAs

- *Evidence-Based Cancer Prevention Services*
  Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.
  Award: Maximum of $1 million over 36 months.

- *Tobacco Control and Lung Cancer Screening*
  Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
  Award: Maximum of $1 million over 36 months.

- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
  Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
  Award: Maximum of $2 million over 36 months.

- *Dissemination of CPRIT-Funded Cancer Control Interventions*
  Seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
  Award: Maximum of $300,000 over 24 months.

Advisory Committees

- The Product Development Advisory Committee met by teleconference on April 11.

- The Clinical Trials Advisory Committee, the University Advisory Committee, and the Product Development Advisory Committee will present their annual reports to the Oversight Committee at its May 15 meeting.

Communications Update

Cancer Awareness Events

- For National Head, Neck and Oral Cancer Month in April, CPRIT featured Dr. Maura Gillison of MD Anderson on our new CPRIT Scholars "card" series. The CPRIT Scholar card is an infographic sent via social media with the CPRIT Scholar's photo and quick facts on their research. The card connects social media users with CPRIT's new Scholars section on the website. The first card in the series featured Dr. Jihye Yun of Baylor College of Medicine in March for Colorectal Cancer Awareness Month.

- Representative Toni Rose cancelled Minority Cancer Awareness Day activities at the Capitol due to a death in her family. Leading up to the April 4th event, Chris Cutrone worked with Rep. Rose's office and the Moncrief Cancer Center to plan activities, including a panel from UT Austin Dell Medical School. Communications will support the event if it is rescheduled.

Special Events

- Communications produced and released a video on childhood cancer featuring interviews with Dr. Stephen Skapek of UT Southwestern and Dr. Ruben Mesa, Director of the UT Health San Antonio MD Anderson Cancer Center.
- Communications is producing a new video showcasing the recent Product Development grantee, Hummingbird, and focuses on the success of CPRIT's Product Development Relocation Awards. The video will feature interviews with Hummingbird leadership and Chief Product Development Officer Cindy WalkerPeach. CPRIT will release the video in early May.

- CPRIT is finalizing discussions with the Austin Convention Center and the Fairmont Austin Hotel in downtown Austin as the venues for the 2020 *CPRIT Innovations VI Conference*. We

will present the details to the Oversight Committee at the May meeting. Conference dates are July 30-31, 2020 and a "Save the Date" will be sent out in May 2019.

Social media

Facebook (last 28 days):
- Reach: 4,969
- Engagement: 1,027
- Most popular post: "Childhood Cancer Awareness in the Texas Legislature: Twelve percent of CPRIT's portfolio goes to childhood cancer research, three times the national rate. Watch UT Southwestern Medical Center's Dr. Stephen Skapek and Dr. Ruben Mesa, Director of the UT Health San Antonio MD Anderson Cancer Center, discuss their work and CPRIT support. Also watch CPRIT Chief Scientific Officer Dr. Willson outline to the Texas Senate progress made in childhood cancer research through CPRIT funding."

Twitter (March):
- 10,000 impressions
- Top tweet: "It's official—Dr. Julian West will join the @RiceUniversity Department of Chemistry July 1 thanks to a $2 million CPRIT Scholar grant: https://cprit.us/2EBFL5W."

Twitter (April 1 - 22):
- 17,900 impressions
- Top tweet: "FYI: State panel OKs referendum plan for more CPRIT funding: https://cprit.us/2HYMdYW."

Operations, Audit and Finance Update

The internal audit team from Weaver completed field work on follow-up procedures to the 2018 post-award grant management and procurement and P-card audits. Weaver has completed the report on the follow-up procedures over post-award grant management and will present it to the Oversight Committee in May. Weaver is completing additional field work on the procurement and P-card processes over the summer to further assess whether CPRIT has implemented procedures to address the finding on payment of the P-card for travel within the 30-day period required by the state.

Subcommittee Meetings

The subcommittees will meet in advance of the May 15 Oversight Committee meeting at the following days/time.

Board Governance	May 2 at 10:00 a.m.
Audit	May 6 at 10:00 a.m.
Academic Research	May 8 at 10:00 a.m.
Product Development	May 9 at 10:00 a.m.
Nominations	May 10 at 10:30 a.m.

CPRIT will send an agenda, call-in information, and supporting material to the subcommittees one week prior to the meeting date.

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CPRIT has awarded **1,372** grants totaling **$2.260 billion**

- 216 prevention awards totaling $235.5 million
- 1,156 academic research and product development research awards totaling $2.025 billion

Of the $2.025 billion in academic research and product development research awards,

- 31.1% of the funding ($630.2 million) supports clinical research projects
- 25.2% of the funding ($510.2 million) supports translational research projects
- 26.3% of funding ($532.0 million) supports recruitment awards
- 14.4% of the funding ($292.7 million) supports discovery stage research projects
- 3.0% of funding ($59.9 million) supports training programs.

CPRIT has 8 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 4 Academic Research
- 1 Prevention

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	MAY 6, 2019

The Chief Compliance Officer is responsible for apprising the Oversight Committee and the Chief Executive Officer of institutional compliance functions and activities, and assuring the Oversight Committee that controls are in place to prevent, detect and mitigate compliance risk. The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules and agency policies. In addition, the Compliance Officer is responsible for monitoring the timely submission status of required grant recipient reports and notifying the Oversight Committee and General Counsel of a grant recipient's failure to meaningfully comply with reporting deadlines.

Submission Status of Required Grant Recipient Reports

CPRIT's grant management system (CGMS) produces a summary of delinquent reports each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 560+ grants that are either active or wrapping up grant activities and receives an average of 560 grantee reports each month.

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Financial Status Report Reviews

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Compliance Specialists have been piloting an Enhanced Desk Review process over the past several weeks. This type of review focuses on grants that have had the same finding year over year in a prior desk review or on-site review. Compliance Specialists are working with one grantee to remediate enhanced desk review findings.

On-Site Reviews

Compliance Specialists conducted four on-site reviews during February, March and April. On-site reviews examine the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance Specialists are working with one grantee to remediate on-site review findings.

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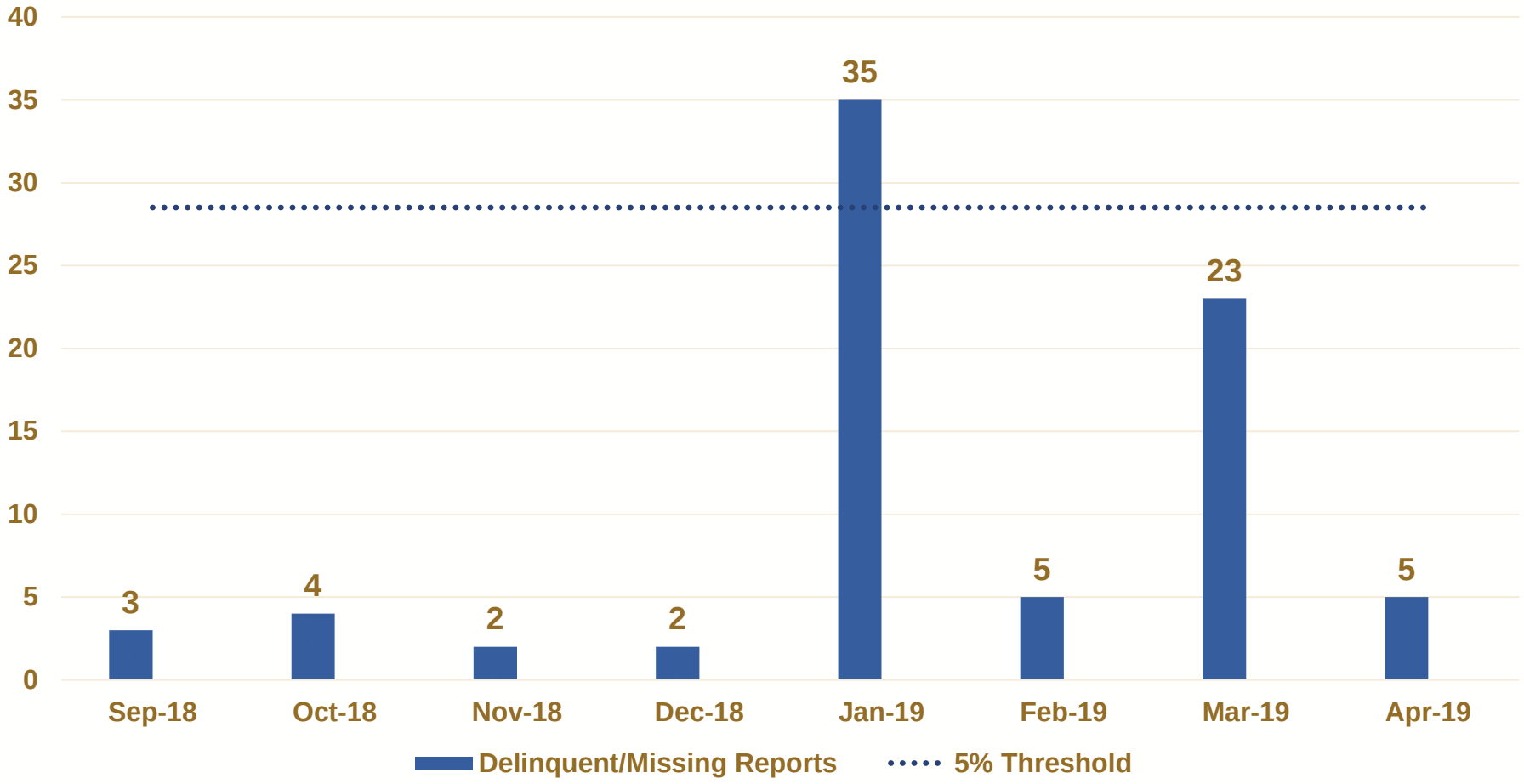
on-site review. Compliance staff is working with two grantees who require additional corrective action related to their attestation.

Training and Support

CPRIT staff conducted the first series of Annual Compliance Training webinars on March 6-7. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. There were approximately 175 grantee staff in attendance. Generally, the trainings cover grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This is the first training series offered this year in support of the annual compliance training requirement which states that the Authorized Signing Official (ASO) and at least one other employee from each grantee organization must attend an annual compliance training by December 31st of each year. A second series of trainings is tentatively scheduled for June 5-6.

CPRIT staff also conducted a new Authorized Signing Official (ASO) training webinar on April 24 for Centro San Vicente, a Prevention grantee. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

Grant Recipient Report Monitoring - 9-18 thru 4-19 Delinquent/Missing Reports



Reports Submitted: Approximately 6,700/Annually, Average 560/Monthly

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE

FROM: JAMES WILLSON, M.D., CHIEF SCIENTIFIC OFFICER

SUBJECT: ACADEMIC RESEARCH FY 2019 RECRUITMENT AWARD RECOMMENDATIONS 19.7, 19.8, AND 19.9.

DATE: MAY 15, 2019

During the FY2019 third quarter (19.7, 19.8 and 19.9), the CPRIT Scientific Review Council (SRC) reviewed 23 recruitment applications (three Recruitment of Established Investigators, nine Recruitment of Rising Stars, and 11 Recruitment of First-Time Tenure Track Faculty Members). The Program Integration Committee (PIC) recommended funding **10** awards totaling **$31,562,426** from the three Scholar mechanisms. Please note that application #RR190038 a Rising Star nomination was recommended by the SRC; however, the application was subsequently withdrawn by the applicant prior to the Program Integration Committee.

The recommendations are presented in three slates corresponding to grant mechanisms and displayed in Table 1.

Table 1: Grant Mechanism	SRC Recommendations	
	Awards	**Funding**
Recruitment of Established Investigators	2	$12,000,000
Recruitment of Rising Stars	2	$7,562,426
Recruitment of First-Time, Tenure Track Faculty Members	6	$12,000,000
Total	**10**	**$31,562,426**

Program Priorities Addressed:
The applications proposed to the Program Integration Committee for funding address the following Academic Research Program Priorities: Recruitment of outstanding cancer researchers to Texas, Computational Biology, Disparities, Hepatocellular Cancer and Implementation Research.

The summarization of program priorities addressed by the proposed slate of awards is displayed in Table 2 and Attachment 1.

Table 2: Program Priorities Addressed by Grant Recommendations		
	Program Priorities	**Funding**
10	Recruitment of outstanding cancer researchers to Texas	$31,562,426
2	Disparities	$5,562,426
1	Implementation research	$3,562,426
1	Computational Biology	$2,000,000
1	Hepatocellular Cancer	$2,000,000
*Some grants awards address more than one program priority and are double counted.		

1. RECRUITMENT of ESTABLISHED INVESTIGATORS SLATE FY 19.7, 19.8 and 19.9.

Peer Review Recommendations
The applications were evaluated and scored by the Scientific Review Council (SRC) to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Purpose of Recruitment of Established Investigators Awards:
Recruits outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.

Funding levels for Recruitment of Established Investigators Awards:
Up to $6 million over a period of five years.

Recommended Awards:
Three Recruitment of Established Investigators grant applications were submitted and The Scientific Review Council recommended two candidates for an Established Investigators Award. Candidates' nominating institutions are: The University of Texas Southwestern Medical Center and Baylor College of Medicine.

Below is a listing of the candidates with associated expertise.

RR190037
Candidate: Suzanne D. Conzen, M.D.
Funding Mechanism: Recruitment of Established Investigators
Applicant Organization: The University of Texas Southwestern Medical Center (UTSW)
Original Organization of Nominee: University of Chicago
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **1.8**
Recommended Total Budget Award and Duration: $6,000,000
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas.

Description:
Suzanne D. Conzen, M.D. is a physician scientist who is being recruited to UT Southwestern as Chief of Hematology/Oncology from the University Chicago where she is Professor of Medicine and a program leader in the Chicago Comprehensive Cancer Center. Her research is focused on the role of the glucocorticoid receptor in prostate, breast and ovarian cancers and has a strong translational rationale as highly specific modulators of the receptor are now in clinical development. She has multiple NCI research grants that she will bring to UTSW.

RR190043
Candidate: Yong Li, Ph.D.
Funding Mechanism: Recruitment of Established Investigators
Applicant Organization: Baylor College of Medicine
Original Organization of Nominee: Cleveland Clinic Lerner College of Medicine
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 2.0
Recommended Total Budget Award and Duration: $6,000,000
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas.

Description:
Dr. Li is recommended for an Established Investigator Award in support of his recruitment to Baylor College of Medicine from the Cleveland Clinic Lerner College of Medicine, Case Western Reserve University. Dr. Li will bring unique expertise in molecular genetics to tackling unsolved questions regarding the intersection of genetics and environment in the etiology of cancer. He currently has 4 active NCI R01 grants focusing on important questions about how inherited factors affect cancer risk of exposure to xenobiotics, herbicides, and other environmental hydrocarbons. The proposed work has far-reaching potential impact from understanding biology, to prevention, to policy.

2. Recruitment RISING STARS SLATE
FY 19.7, 19.8 and 19.9

Peer Review Recommendations
The applications were evaluated and scored by the Scientific Review Council (SRC) to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Purpose of Recruitment of Rising Stars Awards:
The aim is to recruit outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.

Funding levels for Recruitment of Rising Stars Awards:
Up to $4 million over a period of 5 years.

Recommended Awards:
Nine Recruitment of Rising Stars grant applications were submitted and three were recommended by The Scientific Review Council. However, application #RR190038 was withdrawn after the SRC meeting but prior to the Program Integration Committee meeting. Candidates' nominating institutions are: The University of Texas M.D. Anderson Cancer Center and The University of Texas Southwestern Medical Center. Below is a listing of the candidates with associated expertise.

RR190058
Candidate: Qing Zhang, Ph.D.
Funding Mechanism: Recruitment of Rising Stars Award
Applicant Organization: The University of Texas Southwestern Medical Center
Original Organization of Nominee: University of North Carolina Lineberger Comprehensive Cancer Center
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **2.0**
Recommended Total Budget Award and Duration: $4,000,000
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas.

Description:
Qing Zhang, Ph.D., is recommended for a Rising Star Award to support his recruitment to the Department of Pathology at UT Southwestern from the University of North Carolina Comprehensive Cancer Center. Dr. Zhang's research examines how tumors adapt to hypoxia, and how the resultant molecular changes create vulnerabilities for novel therapeutic interventions. Dr. Zhang's research will provide opportunities for collaboration with other CPRIT

grantees at UTSW, including Carlos Arteaga, James Chen and James Brugarolas, and the synergies arising from these collaborations make this a particularly significant recruit.

RR190050
Candidate: Christina Dieli-Conwright, Ph.D., M.P.H.
Funding Mechanism: Recruitment of Rising Stars Award
Applicant Organization: The University of Texas M.D. Anderson Cancer Center.
Original Organization of Nominee: University of Southern California
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **2.6**
Recommended Total Budget Award and Duration: $3,562,426
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas; Implementation research, Disparities

Description:
Christina Dieli-Conwright, Ph.D., M.P.H., is an accomplished exercise physiologist and clinical investigator currently at the University of Southern California (USC) where she studies the role of exercise in cancer as it relates to health care disparities and leads high profile randomized clinical trials on this topic. She is being recruited to MD Anderson with a Rising Star award. Dr. Dieli-Conwright received her doctorate in kinesiology and the M.P.H. at USC and did postdoctoral work at the City of Hope before joining the USC faculty in 2012. She has a strong track record of peer reviewed funding as a clinical investigator and a correspondingly strong publication record. The strong institutional commitment to her recruitment and access to patients provide Dr. Dieli-Conwright and MD Anderson an exceptional opportunity to become a national resource for understanding how to integrate exercise in the management and prevention of cancer.

3. RECRUITMENT OF FIRST-TIME TENURE TRACK FACULTY MEMBERS SLATE FY 19.7, 19.8 and 19.9

Peer Review Recommendations
The applications were evaluated and scored by the Scientific Review Council (SRC) to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, his/her scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Purpose of First-Time Tenure Track Faculty Recruitment
The aim is to recruit and support very promising emerging investigators, pursuing their first faculty appointment in Texas, who have the ability to make outstanding contributions to the field of cancer research.

Funding levels for First-Time Tenure Track Faculty Members Recruitment
Up to $2 million over a period of 5 years.

Recommended Projects:
Eleven Recruitment of First-Time, Tenure Track Faculty Member applications were submitted, and The Scientific Review Council recommended six candidates for Recruitment of First-Time, Tenure Track Faculty Member Awards. Candidates' nominating institutions are Baylor College of Medicine, The University of Texas Southwestern Medical Center and Rice University. Below is a listing of the candidates with their associated expertise.

RR190034
Candidate: Samuel K. McBrayer, Ph.D.
Funding Mechanism: Recruitment of First-Time Tenure Track Faculty Member
Applicant Organization: The University of Texas Southwestern Medical Center
Original Organization of Nominee: Dana-Farber Cancer Institute & Harvard Medical School
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **1.0**
Recommended Total Budget Award and Duration: $2,000,000.
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas.

Description:
Samuel K. McBrayer, Ph.D., is recommended for a First Time Tenure Track Faculty Member Award to recruit him to the Children's Medical Center Research Institute at UT Southwestern. As a Ph.D. student at Northwestern and post-doctoral trainee at Dana Farber Harvard Cancer Institute, Dr. McBrayer published a series of high-profile papers on cancer metabolism, including the discovery of novel therapies for glioblastoma based on metabolic vulnerabilities found in gliomas. At UTSW he plans to continue to focus on glioma and he will have access to outstanding collaborators many who were recruited to UTSW with CPRIT support.

RR190059
Candidate: Chengcheng Jin, Ph.D**.**
Funding Mechanism: Recruitment of First-Time Tenure Track Faculty Member
Applicant Organization: The University of Texas Southwestern Medical Center
Original Organization of Nominee: Massachusetts Institute of Technology
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **1.0**
Recommended Total Budget Award and Duration: $2,000,000
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas

Description:

Chengcheng Jin, Ph.D. is recommended for a First Time Tenure Track Faculty Member Award to recruit her to UT Southwestern from MIT. She received her Ph.D. from Yale and is currently doing her postdoctoral work at MIT. At UT Southwestern she will join the Childrens Medical

Center Research Institute with plans to continue her studies started at MIT on how the microbiome that colonizes the lung can instigate or inhibit lung cancer. Much of this type of work has focused on the intestinal tract; much less has been devoted to the lung and respiratory tract, and her research is a major step towards addressing this gap and to understanding the role of the microbiome in lung cancer development.

RR190046
Candidate: Yang Gao, Ph.D.
Funding Mechanism: Recruitment of First-Time Tenure Track Faculty Member
Applicant Organization: Rice University
Original Organization of Nominee: National Institutes of Health
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **1.0**
Recommended Total Budget Award and Duration: $2,000,000
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas

Description:
Yang Gao, Ph.D. is recommended for a First Time Tenure Track Faculty Member Award to recruit him to Rice from the NIH where he has been highly productive postdoctoral fellow. At Rice he will use biochemical and structural approaches to investigate how mitochondria replicate their genomes. Understanding of mitochondrial DNA replication is of direct relevance to cancer research and therapy and the proposed research is a highly original and timely project which will integrate well with collaborators he has identified as collaborators at MD Anderson and Baylor.

RR190052
Candidate: Xiaojing J Gao, Ph.D.
Funding Mechanism: Recruitment of First-Time Tenure Track Faculty Member
Applicant Organization: Rice University
Original Organization of Nominee: California Institute of Technology
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **1.6**
Recommended Total Budget Award and Duration: $2,000,000
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas

Description:
Xiaojing Gao, Ph.D., is recommended for a First Time Tenure Track Faculty Member Award to recruit him to Rice from Caltech. He received his Ph.D. in biology from Stanford in 2015 and followed by a postdoctoral position at Caltech. As a postdoc, he developed a highly original system for generating protein circuits out of engineered proteins. His long-term research goal is to use these circuits to develop a platform for investigating the behavior of mammalian cells.

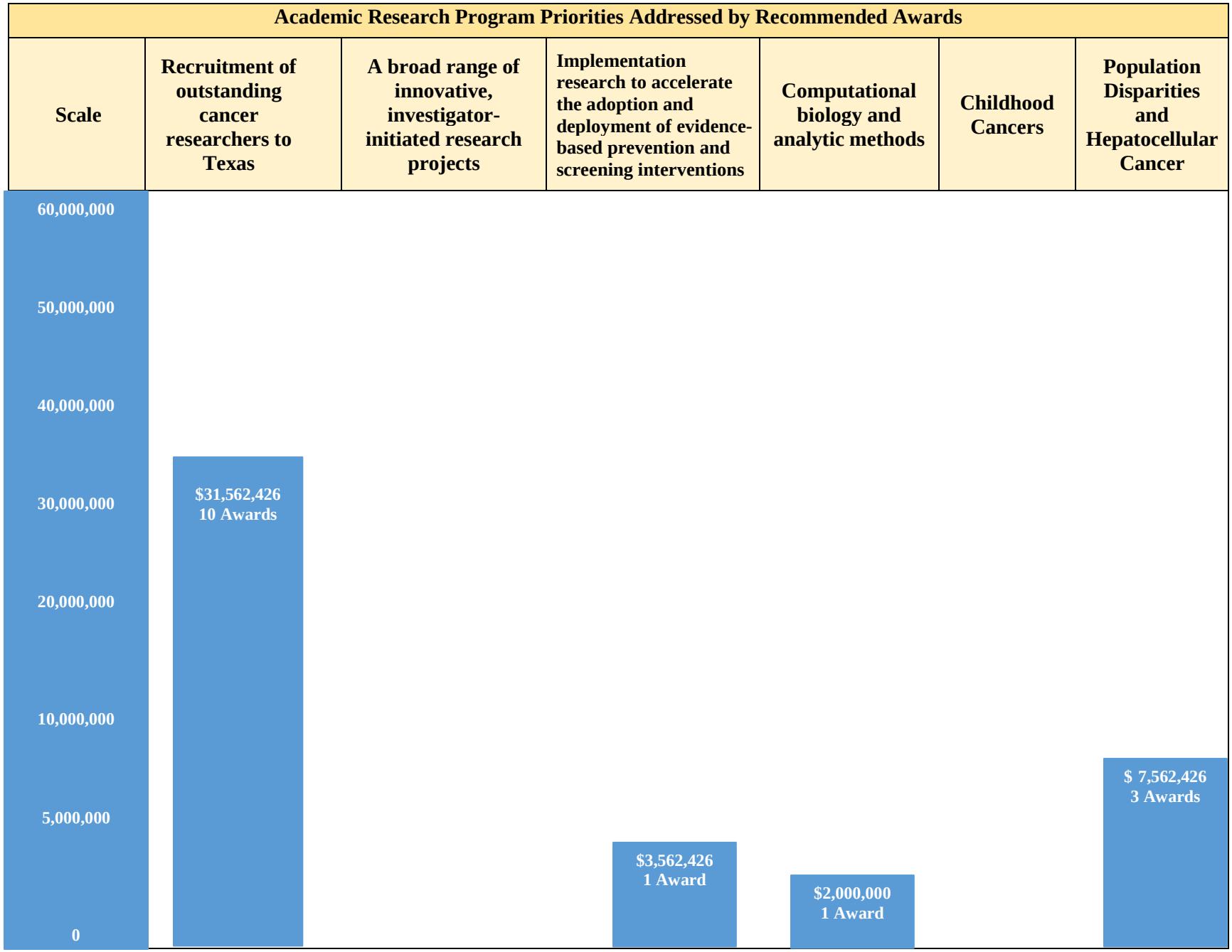
RR190054
Candidate: Anthony M Mustoe, Ph.D.
Funding Mechanism: Recruitment of First-Time Tenure Track Faculty Member
Applicant Organization: Baylor College of Medicine
Original Organization of Nominee: University of North Carolina, Chapel Hill
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **2.0**
Recommended Total Budget Award and Duration: $2,000,000
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas, Computational Biology.

Description:
Anthony Mustoe, Ph.D. is recommended for a First Time Tenure Track Faculty Member Award to recruit him to Baylor College of Medicine from the University of North Carolina (UNC). He received his B.S. in Chemical Engineering at Washington University and a Ph.D. at Michigan, prior to his post-doctoral training at UNC. As a post-doc he developed novel chemical probes and computational programs for analysis of RNA structure. At Baylor his research will address a critical gap in understanding of RNA metabolism, and, given the widespread dysregulation of RNA metabolism in cancer, will likely reveal new mechanisms through which gene expression is usurped during malignancy.

RR190056
Candidate: Kevin J McHugh, Ph.D.
Funding Mechanism: Recruitment of First-Time Tenure Track Faculty Member
Applicant Organization: Rice University
Original Organization of Nominee: Massachusetts Institute of Technology
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **2.0**
Recommended Total Budget Award and Duration: $2,000,000
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas, Liver Cancer, Disparities.

Description:
Kevin McHugh, Ph.D., is recommended for a First Time Tenure Track Faculty Member Award to recruit him to Rice from MIT. Dr. McHugh received his Ph.D. from Boston University and is now a postdoc with Robert Langer at MIT. He has developed a novel nanotechnology which permits continuous targeted therapy over prolonged periods. He plans to use this technology in a novel treatment strategy that targets hepatocellular carcinomas.

Attachment #1



*Some grants awards address more than one program priority and will be double counted.

- **Recruitment of Established Investigators**
  Recruits outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.
  Award: Up to $6 million over a period of five years.

- **Recruitment of Rising Stars**
  Recruits outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.
  Award: Up to $4 million over a period of five years.

- **Recruitment of First-Time Tenure Track Faculty Members**
  Supports very promising emerging investigators, pursuing their first faculty appointment in Texas, who have the ability to make outstanding contributions to the field of cancer research.
  Award: Up to $2 million over a period of five years.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: JAMES WILLSON, MD., CHIEF SCIENTIFIC OFFICER

SUBJECT: ACADEMIC RESEARCH PROGRAM UPDATE

DATE: MAY 15, 2019

FY 2019 Cycle 2 (19.2) Update

CPRIT released 5 RFAs in August 2018 for the second review cycle of FY 2019 (19.2). Table 1 displays an overview of FY 2019 Cycle 2 (19.2) data by mechanism. These applications will undergo peer review in Dallas on May 20- May 24, 2019. Dr. Willson will present the Scientific Review Committee's award recommendations to the Program Integration Committee and the Oversight Committee in August 2019.

Table 1: FY12019.2 Submissions and Funding Requested by Mechanism

FY2019.2 SUBMISSION AND FUNDS REQUESTED DATA		
Funding Mechanism	**# Applications Received**	**Funding Requested**
Core Facilities Support Awards	19	$96,666954
High Impact/High Risk Research Awards	97	$19,379,981
Early Translational Research Awards	28	$47,527,689
Collaborative Action Program to reduce liver cancer mortality in Texas: Collaborative Action Center Award	2	$5,999,901
Collaborative Action Program to reduce liver cancer mortality in Texas: Investigator Initiated Research Awards	15	$36,556,484
Total	**161**	**$206,131,009**

FY 2020 Cycle 1 (20.1) RFAs

CPRIT released FY2020 Cycle 1 RFAs (described below) on January 10, 2019. Applications are due on June 5, 2019. CPRIT has scheduled peer review October 17- 24, 2019 in Dallas. Dr. Willson will present the Scientific Review Council's recommendations to PIC and the Oversight Committee in February 2020.

- **Individual Investigator Research Awards (IIRA)**
  Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications accepted.
  Award: Up to $300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- **Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)**
  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.
  Award: Up to $300,000 per year. Applicants that plan on conducting a clinical trial as part of the project may request up to $500,000 in total costs. Exceptions permitted if extremely well justified; maximum duration: 4 years.

- **Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)**
  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, early-stage progression, and/or early detection of cancer. Research may be laboratory-, clinical-, or population- based, and may include behavioral/intervention, dissemination or health services/outcomes research to reduce cancer incidence or promote early detection. Competitive renewal applications accepted.
  Award: Up to of $300,000 per year for laboratory and clinical research; Up to $500,000 per year for population-based research. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- **Individual Investigator Research Awards for Clinical Translation (IIRACT)**
  Supports applications which propose innovative clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial or involve analyses of biospecimens from patients enrolled on a completed trial for which the outcomes are known. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices.
  Award: Up to $400,000 per year. Maximum duration: 3 years. Applicants that plan on conducting a clinical trial as part of the project may request up to $600,000 in total costs and a maximum duration of 4 years. Exceptions permitted if extremely well justified.

Proposed Scholar RFAs for Fiscal Year 20.1

The Academic Research Program proposes the following schedule and RFAs to be released for Recruitment FY2020.1

Review Cycle	Award Mechanism	RFA Release	Application Receipt	Application Review	Award Notification
Financial Year 2020 - Cycle 1	**Recruitment of First-Time, Tenure-Track Faculty Members** Supports very promising emerging investigators, pursuing their first faculty appointment in Texas, who have the ability to make outstanding contributions to the field of cancer research. Award: Up to $2 million **up to** a period of five years.	Jun 21, 2019	Jun 21, 2019-Jun 20, 2020	Continuous	Continuous
Financial Year 2020 - Cycle 1	**Recruitment of Rising Stars** Recruits outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research. Award: Up to $4 million over a period of five years.	Jun 21, 2019	Jun 21, 2019-Jun 20, 2020	Continuous	Continuous
Financial Year 2020 - Cycle 1	**Recruitment of Established Investigators** Recruits outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas. Award: Up to $6 million over a period of five years.	Jun 21, 2019	Jun 21, 2019-Jun 20, 2020	Continuous	Continuous

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: REBECCA GARCIA, PH.D. CHIEF PREVENTION AND COMMUNICATIONS OFFICER

SUBJECT: COMMUNICATIONS UPDATE

DATE: MAY 15, 2019

The following is an overview of the agency's communication activities.

Earned Media

Coverage (February 15-April 30):

- 9 articles featured CPRIT
- 44 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

Coverage Highlights: (see clipped articles following report)

- February 17, 2019, *San Antonio Express News, CPRIT changing lives of childhood cancer survivors*
- February 22, 2019, *Houston Business Journal, Houston-area physicians, scientists receive a combined $38.1M for cancer research*
- February 26, 2019, *KXAN Austin NBC, Advocates rally at Capitol for cancer research/services funding*
- February 26, 2019, *Houston Business Journal: Houston oncology co. aims to grow after merger announcement*
- February 26, 2019, *NPR San Antonio KSTX, Texas Has A Robust Savings Account. Here's How Some Would Like To Spend It.*
- March 22, 2019, *The Cancer Letter: Texas Cancer Researchers Vying To Renew CPRIT Beyond Its 2023 Sunset Date*
- March 22, 2019, *The Cancer Letter: Q&A: James Willson: CPRIT is money well spent*
- March 29, 2019, *El Paso Inc., TTUHSC El Paso: Tackling diabetes, cancer*
- April 1, 2019, *Corpus Christi Caller-Times, A cancer survivor's plea to the Texas Legislature: Keep funding the research*
- April 3, 2019, *Austin American-Statesman, Senate Panel OKs referendum plan for more CPRIT funding*
- April 16, 2019, *TribTalk, The New Driving Force of the Texas Economy*
- April 16, 2019, *KXAN Austin NBC, Texas House approves bills to secure future of cancer research agency*
- April 28, 2019, *Austin American-Statesman, Keep Texas at the forefront of the fight against cancer*

Cancer Awareness Events

- For National Head, Neck and Oral Cancer Month in April, Dr. Maura Gillison of MD Anderson was featured on the new scholars "card" series. The scholar "card" is an infographic sent via social media with a scholar's photo and quick facts on their research. The card is meant to connect social media users with our new scholars section on the website. The first card in the series featured Dr. Jihye Yun of Baylor College of Medicine in March for Colorectal Cancer Awareness Month.

- Representative Toni Rose cancelled Minority Cancer Awareness Day activities at the Capitol due to a death in her family. Leading up to the April 4th event, Chris Cutrone worked with Rep. Rose's office and the Moncrief Cancer Center to plan activities, including a panel from UT Austin Dell Medical School. Communications will support the event if it is rescheduled.

Special Events

- Timed to coincide with Dr. James Willson's testimony on childhood cancer for SB 2014 and SB 2015 at the Senate Transportation Committee on April 10, Communications produced and released a video on childhood cancer featuring interviews with Dr. Stephen Skapek of UT Southwestern and Dr. Ruben Mesa, Director of the UT Health San Antonio MD Anderson Cancer Center.

- The next video Communications is producing showcases the recent Product Development grantee, Hummingbird, and focuses on the success of CPRIT's Product Development Relocation Awards. The video will feature interviews with Hummingbird leadership and Chief Product Development Officer Cindy WalkerPeach. The video will be released in early May.

- CPRIT is finalizing discussions with the Austin Convention Center and the Fairmont Austin Hotel in downtown Austin as the venues for the 2020 CPRIT *Innovations VI Conference*. Conference dates are July 30-31, 2020. Staff will present a recommendation for a contract with Austin Convention Center Catering for food and beverage services as well as other details about the conference. A "Save the Date" will be sent out in May after the Oversight Committee meeting. Heidi McConnell has agreed to assume overall responsibility for the conference. Chris Cutrone's key responsibilities will continue to be speaker communication, promotion, and media and grantee interviews.

Other activities

- Chris Cutrone worked with a reporter with *The Cancer Letter* on an article that was released March 22. Dr. Willson was interviewed for the article, and it featured interviews with Dr. Pisters from MD Anderson, Dr. Osborne from Baylor College of Medicine and Dr. Arteaga from UT Southwestern. Generally viewed as a positive piece, the article had nationwide distribution.

- Wayne Roberts was interviewed by *Houston Chronicle* health affairs reporter Todd Ackerman on April 4. The questions centered on the future of CPRIT in the context of Rep. John Zerwas's HJR 12 reauthorization and SB 200 self-sufficiency bills. Rep. Zerwas was also interviewed by Mr. Ackerman. A story has not been published at this time.

- On April 8, Communications provided written responses to questions from a *Texas Tribune* reporter about HJR 12 and HB 39. A story not been published at this time.

- Communications is posting updates in the newsroom and via social media as bills related to CPRIT move through the Texas Legislature.

Social Media

Facebook (last 28 days/April 4-May 1):

- Reach: 3,739
- Engagement: 1,114
- Most popular post: Childhood Cancer Awareness in the Texas Legislature: Twelve percent of CPRIT's portfolio goes to childhood cancer research, three times the national rate. Watch UT Southwestern Medical Center's Dr. Stephen Skapek and Dr. Ruben Mesa, Director of the UT Health San Antonio MD Anderson Cancer Center, discuss their work and CPRIT support. Also watch CPRIT Chief Scientific Officer Dr. Willson outline to the Texas Senate progress made in childhood cancer research through CPRIT funding.

Twitter (April):

- 26,600 impressions
- Top tweet: FYI: State panel OKs referendum plan for more CPRIT funding: https://cprit.us/2HYMdYW.

Metrics Tracking

	Facebook		Twitter		Website	
2019	**Reach**	**Engagement**	**Impressions**	**New Followers**	**Unique Vistors**	**Sessions**
January	3,334	515	18,200	12	6,100	8,700
February	1,305	370	21,900	51	6,200	9,100
March	4,969	1,027	10,000	22	4,800	6,900
April	3,739	1,114	26,600	33	5,100	7,400
	Number of people who had any of our posts enter their screen	Number of times people engaged with our posts (likes, comments, shares, etc.)	Number of times users saw our tweets	Number of new people or organizations that elected to follow us on Twitter	Number of people that visited the website	Number of times people visited the website

CPRIT changing lives of childhood cancer survivors

By Angela Lee, For the Express-News Published 12:00 am CST, Sunday, February 17, 2019

Imagine being 13 years old and hearing these words: "It's cancer."

That was me back in 1984. What followed was a long process of tests, surgeries and treatments, all necessary for me to survive. Those were difficult days. Days that changed the course of my life forever.

When I heard the doctors tell me I was "cured" in September 1989, I truly thought the battle was over. Finally, I wouldn't need to think about daily trips to medical facilities 90 minutes away, radiation treatments and medical follow-ups.

Little did I know, a new journey was just beginning. And that journey would have an adverse impact on my body for the rest of my life.

You see, as a childhood cancer survivor, there were tremendous obstacles that prevented me from living a "normal" life. There was virtually no way for me to ensure my adult doctors understood the details of my cancer battle. They didn't know the treatments I had withstood and didn't have access to the long list of long-term side effects that were possible from all the radiation I endured.

I had to become my own advocate. Despite having no medical training, I had to explain my health history, do my own research and carry around hard copies of all my medical records. I was left to repeat my story to specialist after specialist, hoping I was giving them the details that they needed to keep me on a healthy path. I often thought, "Can't there be another way to store this data and provide it to my doctors?"

The Cancer Prevention and Research Institute of Texas, or CPRIT, was created by the Texas Legislature and voters back in 2007 to foster breakthroughs in cancer research, treatment and prevention. Each year, the program awards $300 million in grants to Texas institutions through a peer-reviewed competitive basis. One of its earliest grants was awarded to Baylor College of Medicine to tackle the problem that childhood cancer survivors like me were facing.

The Passport for Care is a web-based tool for health care providers to use when they are treating survivors of childhood cancer. The technology allows doctors to extract patient medical records with a few clicks of the mouse. They can see treatment summaries, individualized evidence-based screening guidelines and specific follow-up information. The passport ensures that childhood cancer survivors get the highest level of care, no matter where they live.

Unfortunately, unless the Texas Legislature acts during the 2019 session, CPRIT funding will decline dramatically, bringing to a halt much of the progress that it has made in prevention and treatment. And any interruption in funding may jeopardize the progress that has been made on projects like the Passport for Care.

The Legislature needs to immediately provide $600 million in funding for the next two years to ensure CPRIT can sustain its current level of grant funding. Additionally, the Legislature must pass a bonding authority bill that would allow Texas voters to decide whether CPRIT should receive an additional $3 billion over the next 10 years.

A recent poll commissioned by the American Cancer Society Cancer Action Network indicates that 70 percent of Texans would favor a constitutional amendment that would reauthorize the Legislature to issue $3 billion worth of bonds to fund CPRIT for an additional 10 years. Support reaches across party lines and is strong in every part of our state.

This issue is about more than me and the thousands of childhood cancer patients who are diagnosed and treated every year. There are 15.5 million cancer survivors living today in the U.S., and more than a million of those live in Texas. With continued funding, CPRIT's Passport for Care program could become an essential tool to ensure all of them receive appropriate long-term care after remission.

In the coming weeks, our elected officials will have the chance to vote on House Joint Resolution 12, which would give Texans the opportunity to vote on whether to authorize $3 billion in bonds to fund CPRIT for another decade. Without this bill, the program will likely sunset in 2021. Please join me in asking your state representatives to support this bill.

Angela Lee of San Antonio is a volunteer with the American Cancer Society Cancer Action Network.

HOUSTON
BUSINESS JOURNAL

Houston-area physicians, scientists receive a combined $38.1M for cancer research

By Chris Mathews – Reporter, Houston Business Journal
Feb 22, 2019, 3:44pm EST

Physicians and scientists from several major Houston-area health systems received millions in grant funding from The Cancer Prevention and Research Institute of Texas, according to a Feb. 21 release from CPRIT.

CPRIT awarded 54 new academic research, prevention and product development grants totaling nearly $96 million, and Houston nabbed some $38.1 million.

The University of Texas M.D. Anderson Cancer Center was awarded $19.6 million to support research, recruitment and prevention efforts. M.D. Anderson's funding totalled some 20 percent of the entire $96 million given out by CPRIT.

M.D. Anderson's research awards include $12 million for individual investigator research, with projects aimed at clinical translation research, cancer prevention and early detection studies. The cancer center received $4 million for recruitment, and $3.6 million for tobacco cessation and expansion of cervical cancer prevention in medically underserved populations, according to a release from M.D. Anderson.

“Since it began providing much-needed support to Texas cancer research institutions, M.D. Anderson has benefitted through funding for critical areas of need," said M.D. Anderson president Peter WT Pisters in a release from the cancer center. "I am particularly pleased that CPRIT has earmarked vital funding for preventive outreach and study for those who are medically underserved. This emphasis, along with significant research and recruitment support, aids us in our effort to end cancer.”

Researchers from Baylor College of Medicine and its affiliate Texas Children's Hospital received a combined $9.3 million for seven projects aimed at prevention for breast cancer, childhood cancers, T Cell therapy and lung cancer, according to a release from Baylor College of Medicine.

The University of Texas Medical Branch at Galveston was awarded three grants, totaling some $6 million. The University of Texas Health Science Center at Houston was awarded two grants, totaling $1.2 million. Rice University received a $2 million recruitment grant to land a researcher from the California Institute of Technology, according to the CPRIT release.

Several grants went to Dallas-based researchers, and San Antonio-area researchers received $3 million in funding, according to the HBJ's sister paper San Antonio Business Journal.

CPRIT was approved by Texas voters in 2007 to issue $3 billion in grants for cancer research and prevention programs and services in the state. During the 85th Texas Legislature, the institute's sunset review date was extended by two years to 2023 to enable the agency to exhaust the funds approved by Texas voters.

Advocates rally at Capitol for cancer research/services funding

by: Phil Prazan, Russell Falcon
Posted: Feb 26, 2019 / 02:21 PM CST / Updated: Feb 26, 2019 / 05:48 PM CST

AUSTIN (KXAN) — The Cancer Prevention and Research Institute of Texas — infrastructure for research and cancer fighting services — will end after this state budget unless authorized by the Texas legislature and approved by Texas voters.

Around 150 advocates for the American Cancer Society walked the halls to the state Capitol Tuesday to convince lawmakers to support CPRIT for ten more years.

The Texas capitol can be loud, hectic, and crowded. At this time during the legislative session lobbyists and advocates walk the halls to push their cause. For Jackie Bush, her cause is personal.

She's been fighting breast cancer since 2002 and it just came back, for the fourth time.

"I want to be around for a long time. I have little baby grand kids and I want to see them grow up. I don't want them to hear that they have cancer," said Bush.

Tuesday, she chose to be in the capitol corridors instead of in a doctor's office for day one of another round of chemotherapy. She says CPRIT funded the immunotherapy research that saved her eyes when the cancer spread there.

"I still have my sight in the my eye because of that. So it's very important for us to make sure that this research continues on," said Bush, hoping the money continues for the next generation.

Since the agency started a decade ago, 170 cancer researchers have moved to Texas, says Gray.

"There are a lot of important issues in this building. We are really trying to make sure this stays a priority and competes with these other really important issues. And we know it does," said Gray.

14,000 people in Texas are in trials funded through the agency, says James Gray, the Government Relations Director from the American Cancer Society.

CPRIT will end after this next budget cycle in 2022 unless lawmakers decide to continue it. Not only must lawmakers reauthorize CPRIT for the next ten years, they also must pay for it this year.

The two top budget writers are Chair of Senate Finance, Jane Nelson, R-Flower Mound, and Chair of House Appropriations, John Zerwas, R-Richmond. Both support CPRIT. The House puts $600 million toward it this budget. The Senate, more than $430 million, which is the amount remaining from what voters approved ten years ago.

Rep. Zerwas is carrying the bill to reauthorize it for another decade, by taking out $3 billion in bonds. Sen. Nelson wants the legislature this session to look at how much it funds the program and how it should going forward.

Lawmakers will look over the details carefully because grants haven't always gone smoothly through CPRIT.

In 2012, an oversight committee disclosed that CPRIT had approved 11 million dollars in grants to Peloton Therapuetics without a proper review. The agency's grant-making powers were temporarily suspended. After that, some lawmakers pushed legislation to reduce financial assistance from the state. That legislation did not pass.

Lawmakers must pass this year's budget by the end of May.

HOUSTON
BUSINESS JOURNAL

Houston oncology co. aims to grow after merger announcement

By Chris Mathews – Reporter, Houston Business Journal
a month ago

Houston-based Salarius Pharmaceuticals LLC, a clinical-stage oncology company, is hiring for administrative, financial and clinical roles following a merger announcement.

Salarius Pharmaceuticals announced plans to merge with Boston-based Flex Pharma Inc. (Nasdaq: FLKS) in a Jan. 4 press release. The merger, expected to close in the first half of 2019, should create a new combined company called Salarius Pharmaceuticals Inc.

Salarius Pharmaceuticals CEO David Arthur told the Houston Business Journal that the company is hiring for a director of clinical operations, a director of biology, an executive assistant-office manager and some employees in financial roles. He said that as the company prepares to go public, Salarius is in need of financial officers that are experienced in working with publicly traded firms.

The company has 10 employees.

"As you can imagine, moving from a private to a public organization requires a very different set of skills," Arthur told the HBJ. "These [mergers] happen, and companies grow. It's a great thing for the Houston environment."

Arthur said that Salarius will not maintain an office presence in Boston after the deal closes. Flex Pharma President and CEO William McVicar will join the Salarius board of directors, Arthur said.

"Boston, San Diego and San Francisco are all biotech hubs – but we're beginning to turn Houston into a hub," Arthur said. "We don't have a need for a Boston presence from a business perspective. But we do have a clinical trial site in Boston."

Regarding the status of the merger, Arthur said that all of the moving pieces are progressing smoothly – unlike the planned merger between Houston-based Memorial Hermann Health System and Dallas-based Baylor Scott & White Health, which fell through earlier in February. Once the merger is approved by the SEC and signed off by both Flex's shareholders and Salarius' members, the company will change names to Salarius Pharmaceuticals Inc. and will receive a new stock symbol.

When the deal closes later this year, Flex Pharma stockholders and current Salarius investors will own approximately 19.9 percent and 80.1 percent of the combined company, respectively. Arthur said that Salarius will still have $9.1 million remaining on an award given by the Cancer Prevention & Research Institute of Texas when the deal closes, and that the company recently closed on a $6.4 million Series A round. He said that Salarius expects Flex Pharma to bring between $3.5 million and $4 million when the merger is complete.

The deal valued Flex Pharma at $10.5 million and Salarius at $36.6 million, according to a filing with the U.S. Securities and Exchange Commission. Salarius Pharmaceuticals has an office inside of Johnson & Johnson's JLABS at the Texas Medical Center Innovation Institute.

Salarius Pharmaceuticals relocated from Salt Lake City to Houston in 2016 following an $18.69 million grant from CPRIT.

Texas Has A Robust Savings Account. Here's How Some Would Like To Spend It.

By BEN PHILPOTT, KUT NEWS & BEN PHILPOTT, KUT NEWS • FEB 26, 2019

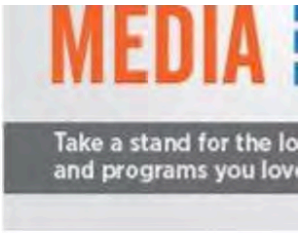
The Texas Economic Stabilization Fund, often called the rainy day fund, is doing well. Really well, actually. By the end of 2021, Texas Comptroller Glenn Hegar projects, it will have about $15 billion in it. Lawmakers say the account needs to have a minimum of $7.5 billion to help the state maintain a top credit rating.

What should happen to the rest of that money?

There are several suggestions. And in the end, some of it will be spent. Let's run down a list of the different players asking for money, and what they'd like to spend it on.

The comptroller is the keeper of the piggy bank. Since Hegar was first elected in 2014, he's been pushing for more investment. He says much of the money in the billion-dollar account doesn't make enough on interest to keep up with inflation. He wants to take about $4.5 billion from the account and invest it, hopefully bringing in a higher return.

Hegar wants to then take that return and use it to help stabilize the state's retirement systems.



A draft version of the House budget would take $633 million from the rainy day fund and spread it out over several areas, including: $230 million to help lower premiums for the Teachers Retirement health care plan; $164 million for the Cancer Prevention and Research Institute of Texas; and about $43 million to improve school safety.

The upper chamber would spend more from the fund. Its initial proposal would take $2.5 billion and put $2 billion toward Hurricane Harvey rebuilding, $300 million for the Teachers Retirement and State Employees Retirement systems, and $100 million toward improving security in public schools.

Last week, House Democrats released a plan to increase public school funding, taking $1.75 billion from the rainy day fund. Almost all that money would be used to stabilize the Teachers Retirement System, with about $180 million going toward $500 checks for teachers to buy school supplies. Many teachers use their own money to buy items needed in their classrooms.

The conservative think tank has long been opposed to spending money from the fund. In a report released in December, the group laid out provisions that would make it harder to authorize any spending. That includes requiring a four-fifths vote of both the House and Senate to use rainy day fund money.

The group is OK with the comptroller's plan to invest part of the fund to get a better return. But it'd rather see changes made to the pension system before allowing investment income to prop up those systems.

It also suggests taking some of the tax dollars directed to the fund and using the money to try to lower local property taxes.

This progressive state policy think tank has advocated for using the rainy day fund for times when money is NOT raining on the state. In previous sessions when tax revenues have dropped, the CPPP pushed the idea of spending some of the fund to limit budget cuts.

Cuts are not on the table this session, and the group supports the current spending proposals laid out in the draft House and Senate budget.

The House and Senate usually try to pass their versions of the budget as soon as possible. That gives lawmakers plenty of time to reconcile the differences between the two bills before the legislative session ends May 27.

TCL
THE CANCER LETTER

Inside information on cancer research and drug development

Vol. 45 No. 12

MARCH 22, 2019

www.cancerletter.com

TEXAS CANCER RESEARCHERS VYING TO RENEW CPRIT BEYOND ITS 2023 SUNSET DATE

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TEXAS CANCER RESEARCHERS VYING TO RENEW CPRIT BEYOND ITS 2023 SUNSET DATE

THE INSTITUTE IS SPENDING MORE THAN NCI IN THE STATE

By Claire Dietz and Matthew Bin Han Ong

The Cancer Prevention and Research Institute of Texas—the second largest publicly-funded granting organization for cancer after NIH—may receive $3 billion more to stay open past its current sunset date in 2023.

The Texas state legislature is considering bills designed to repeal time limitations on CPRIT—Senate Bill 438, led by Texas Sen. Jane Nelson, and House Bill 39, led by Texas Rep. John Zerwas.

House Joint Resolution 12, also led by Zerwas, would authorize another $3 billion in general obligation bonds for cancer research and prevention to be submitted to voters at the general election on Nov. 5.

If these bills are passed, CPRIT will once again be put to the ballot, and Texas voters will be asked to approve another constitutional amendment, a requirement for reauthorizing the institute.

In their current versions, the House and Senate bills don't specify the number of years for CPRIT's reauthorization.

In fiscal year 2018, Texas institutions received $276 million from CPRIT and $250 million from NCI.

Over the years, funding from CPRIT allowed Texas institutions to attract top-tier researchers, including, famously, James Allison, who won the 2018 Nobel Prize in Physiology or Medicine for his work on immune checkpoint inhibition.

Allison was recruited to MD Anderson from Memorial Sloan Kettering Cancer Center in 2011. He is now chair of the Department of Immunology, the Vivian L. Smith Distinguished Chair in Immunology, director of the Parker Institute for Cancer Research, and the executive director of the Immunotherapy Platform at MD Anderson.

"It's very gratifying to hear from the state leadership, both the recognition of what CPRIT has accomplished and, in addition, the understanding of what's ahead of us in terms of continued opportunity to make an impact in cancer in Texas," James Willson, CPRIT chief scientific officer, said to The Cancer Letter. "And that leads us to be quite optimistic about the future continuation of this investment."

A conversation with Willson appears on page 14.

"CPRIT has had an extraordinary impact on MD Anderson in innumerable ways," Peter Pisters, president of MD Anderson Cancer Center, said to The Cancer Letter. "It has helped us to attract faculty, it has helped us to foster research, and it has helped us to advance prevention efforts, which is a crucial part of our mission.

"The ability to recruit excellent talent has extended across the state, as CPRIT has been responsible for 170 scientists coming to Texas," Pisters said. "They're coming here as a result of a voter-approved process to allocate $3 billion in resources to cancer prevention and research—positioning CPRIT as the second largest government funder of cancer research in the world, after the NIH."

CPRIT is one of a kind, said Richard Kolodner, chair of the Scientific Review Council at CPRIT, director of the Ludwig Institute for Cancer Research San Diego Branch, and Distinguished Professor at the Department of Cellular and Molecular Medicine at the University of California San Diego School of Medicine.

"I think that in different ways many states do provide research funding, but not generally at this scale or at this level of organization. There is the California stem cell program, which I don't know very much about, but that I think is worthwhile," Kolodner said to The Cancer Letter. "I think the scientific review board is universally positive about CPRIT, and I think everybody would be in favor in continuing the program pretty much as is."

Founded in 2007, CPRIT was initially authorized $3 billion in bonds toward funding research and prevention programs throughout Texas. Since its formation, CPRIT has awarded more than $2.26 billion in grants to Texas researchers, institutions, non-profit organizations and businesses.

"We see that CPRIT has elevated the caliber of cancer research and prevention across the entire state of Texas and benefited 28 million people in a state, which is now on a trajectory to reach 50 million people by 2050," MD Anderson's Pisters said. "In the creation of CPRIT, you can see the wisdom of our legislators as they are preparing for not only diversification of our economy, but the change in population that's going to happen here, and the reality of providing state-of-the-art services around prevention and treatment in Texas."

According to a recent study of CPRIT's impact on the state economy, every dollar spent through the institute for screening and prevention saves $1.94 in direct health spending and leads to a total of $25.75 in treatment cost savings and resulting economic benefits through earlier detection.

The 2018 report by the Perryman Group sought to estimate both the cost of cancer and the impact of CPRIT on Texas. The cost of cancer in Texas was estimated to be $40.3 billion in 2018 (about $1.5 billion higher than in 2017), with total economic losses (including spinoff effects) of an estimated $104.6 billion in output, as well as 1,064,595 jobs.

CPRIT commissioned the report in order to comply with the requirements of its governing statute.

The current total annual impact of CPRIT on Texas business activity was estimated at $22.3 billion in annual spending, $12.4 billion in output each year, and 110,265 jobs in 2018.

In February 2019, the institute awarded 42 new academic research grants, seven prevention grants, and five product

development grants totaling close to $96 million. CPRIT's initial sunset date was set for 2021, but it has since been extended to 2023.

CPRIT has also requested a $164 million increase to its budget for fiscal years 2020 and 2021, up from $198 million per year to sustain its current level of effort in grant making.

If CPRIT's budgetary request is granted, the agency would receive an additional $82 million per year over the next two years. CPRIT grants are funded at $280 million in FY19, and the increase is needed in order to maintain grant program current services resulting from the decline in general obligation bond proceeds, CPRIT officials said to the Texas Senate Committee on Finance at a hearing Jan. 23.

"CPRIT is running out of bond authority to make new grants, and 2019 is the last year we will be able to award our historical average of $280 million in grants," Chris Cutrone, senior communications specialist at CPRIT, said to The Cancer Letter. "In 2020–21, we will have enough authority left to provide $198 million each year. Therefore, we're asking the legislature for $164 million to fill this 2020–2021 gap to maintain our current momentum. If granted, this would be a stop-gap measure until a permanent funding source is identified and provided."

Another measure, Senate Bill 200, led by Sen. Charles Schwertner, would mandate CPRIT to develop a "financial self-sufficiency plan" and submit the plan to the legislature by Dec. 1, 2020.

"The institute shall develop a detailed plan for the institute to become financially self-sufficient and to continue operations without state funds other than patent royalties and license revenues realized as a result of projects undertaken with money awarded," the bill states.

In fiscal year 2018, CPRIT operations and programs generated a sizable increase in business activity in Texas, including $719.8 million in output (gross product) and 10,132 jobs.

"The commitment of Texas voters and the vision of the Texas legislature in establishing CPRIT, and the benefits of it, extend far beyond the scientific contributions—it also includes significant economic impact on Texas," Pisters said. "The estimates by a third-party economic evaluation of the program suggest that 10,000 jobs are created per year in Texas as a result of CPRIT."

Without CPRIT, it would be harder to attract researchers to Texas, said Carlos Arteaga, a member of the Clinical Trials Advisory Committee at CPRIT and director of the Harold C. Simmons Comprehensive Cancer Center.

"From talking to people on the outside, [there is] the notion that we can provide significant catalytic resources from junior, mid-level, or senior faculty that come to Texas from the Northeast, from California, from other parts of the country," Arteaga said to The Cancer Letter. "I think it is a nice inducement, or incentive, that makes our job of recruitment easier."

THE CURRENT IMPACT OF CPRIT DIRECT OPERATIONS, PREVENTION AND SCREENING, AND RESEARCH PROGRAMS ON TEXAS BUSINESS ACTIVITY AND TAX RECEIPTS

(Monetary Values in Millions of Constant 2018 Dollars)

ECONOMIC BENEFITS				
	Operations	Prevention & Screening	Research	TOTAL
Total Expenditures	$31.5	$117.0	$1,232.8	$1,381.3
Gross Product	$16.0	$63.7	$640.1	$719.8
Personal Income	$11.0	$44.6	$443.4	$499.0
Retail Sales	$4.2	$16.7	$168.6	$189.5
Employment (Permanent Jobs)	$142	794	9,196	10,132
FISCAL BENEFITS				
State (Texas)	$0.8	$3.1	$32.7	$36.7
Local Governmental Entities Throughout the State	$0.4	$1.7	$19.3	$21.4

Note: Columns may not add to total due to rounding.

– Source: The Perryman Group

CPRIT is responsible for attracting cutting-edge research programs to Texas, said Kolodner.

"If you bring the right researchers, you bring in the right research programs, you can make different kinds of impact on the research that's being done in Texas," Kolodner said to The Cancer Letter. "There's no institution or state that has a monopoly, or has representation of all the types of expertise, methodologies, and instrumentation that one needs to do science in the modern age."

CPRIT funding has also led to the creation of many startups in Texas, said Kent Osborne, vice chair of the University Advisory Committee at CPRIT and director of the Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine.

"In the product development area, there have been 30 companies that have been funded," Osborne said to The Cancer Letter. "Twelve of those are new to Texas. They were brought into Texas because of CPRIT funding. The others were new startups or expanded startups in the state. They've also had a considerable amount of follow up funding in terms of venture capital, and other grants that the companies themselves will receive."

Seven years ago, CPRIT ran into a series of problems involving conflicts of interest, which resulted in a moratorium on its activities between December 2012 and October 2013.

The controversy came into public view when CPRIT's Chief Scientific Officer Alfred Gilman, a Nobel laureate who is credited with having designed CPRIT's peer review mechanism, resigned in protest against political meddling.

After Gilman quit, the vast majority of scientists he recruited to conduct peer review followed him out the door. Many of them returned after the organization received what can be best described as a reboot.

The CPRIT scandal was covered in real time by The Cancer Letter and recapped in a 14-part series of stories titled "Slamming the Door; How Al Gilman Taught Texas a Lesson in Science."

"I have always been very positive about CPRIT and that's why, when there was this moment when some people got upset—well, I think probably everybody got distressed about things—some people sort of terminated their involvement, but for all of us in science, there's sort of a public service element," Kolodner said to The Cancer Letter.

"Some people stayed and some new people were recruited, and I think that process of turnover in the scientific review board is really a good thing. New personalities, new expertise, new ideas on a committee like that, I think, really, is helpful to the program because of new opinions about what's important."

CPRIT's impact should give the "legislators a clear sense that it is too important to fail," said James Gray, managing director of government relations at American Cancer Society Cancer Action Network in the organization's South Central Region.

Over the past decade, "it has become very clear that CPRIT has done more than anybody expected," Gray said to The Cancer Letter. "You've got this idea of bringing 170 researchers to the state of Texas because of funding the idea of testing and product development that would create new therapies for cancer."

In the coming months, CPRIT officials and cancer researchers in the state are scheduled to appear before the Texas House Committee on Public Health.

"Looking to the future of the program, we've met with many legislators, and we're encouraged by what we are hearing," Pisters said. "If CPRIT is reauthorized, it would then go to the voters in Texas again this fall."

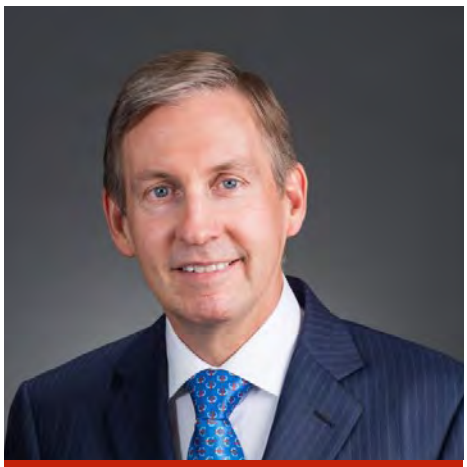
CPRIT was scheduled to sunset by the end of fiscal 2021. On June 9, 2017, Texas Governor Greg Abbott signed Senate Bill 81, which extended the organization's Sunset Review date to Sept. 1, 2023.

If the bills to repeal time limitations and authorize a second $3 billion in general obligation bonds submitted to voters at the general election on Nov. 5, 2019 don't pass this session, the legislative process may extend into the 2021 legislative session.

"The uniqueness of this program, its ability to do product development, translational research, bench research, recruit volunteers and prevention programs. I actually think we are the envy of 49 other states," Gray said.

"There is overwhelming support in the legislature to continue CPRIT," Gray said. "Even those that were opposed to it philosophically in 2007 have really gotten to the point where they understand the impact and the reach that this organization has had.

"This is going to be a generational agency," Gray said. "This is an agency that's going to continue to be the fabric of state government."



Peter Pisters
President, MD Anderson Cancer Center

> And thus, we see that CPRIT has elevated the caliber of cancer research and prevention across the entire state of Texas and benefited 28 million people in a state which is now on a trajectory to 50 million by 2050.

CPRIT has had an extraordinary impact on MD Anderson in innumerable ways. It has helped us to attract faculty, it has helped us to foster research, and it has helped us to advance prevention efforts, which is a crucial part of our mission.

And, as you know, a very intrinsic and fundamental part of CPRIT as a program is that is has enabled us to bring 30 faculty to MD Anderson—that's CPRIT scholars, including Dr. James Allison, who was recently recognized with a 2018 Nobel Prize for his contributions in immunology.

The ability to recruit excellent talent has extended across the state, as CPRIT has been responsible for 170 scientists coming to Texas. They're coming here as a result of a voter-approved process to allocate $3 billion in resources to cancer prevention and research—positioning CPRIT as the second largest government funder of cancer research in the world, after the NIH.

That speaks volumes. The commitment of Texas voters and the vision of the Texas legislature in establishing CPRIT, and the benefits of it, extend far beyond the scientific contributions—it also includes significant economic impact on Texas.

The estimates by a third-party economic evaluation of the program suggest that 10,000 jobs are created per year in Texas as a result of CPRIT.

If you look at the CPRIT metrics at MD Anderson, we've received $290million for core facilities for early translational research and research training, including high-impact, high-risk investigator-initiated work. When you look at the totality of CPRIT's impact on MD Anderson, thus far it's just about $450 million.

One of the most important aspects of that figure is that it is only 20 percent of CPRIT's total funding.

And thus, we see that CPRIT has elevated the caliber of cancer research and prevention across the entire state of Texas and benefited 28 million people in a state which is now on a trajectory to reach 50 million people by 2050.

In the creation of CPRIT, you can see the wisdom of our legislators as they are preparing for not only diversification of our economy, but the change in population that's going to happen here, and the reality of providing state-of-the-art services around prevention and treatment in Texas.

Looking to the future of the program, we've met with many legislators, and we're encouraged by what we are hearing. If CPRIT is reauthorized, it would then go to the voters in Texas again this fall.

Kent Osborne
Vice chair, University Advisory Committee, CPRIT; Director, Dan L Duncan Comprehensive Cancer Center, Baylor College of Medicine

> Right now, we have about $30 million in CPRIT grants here at Baylor. We've benefited in terms of being able to recruit new scholars to our institution of cancer researchers.

Perhaps the most tangible health benefit is prevention efforts, which is not research, but screening and education in the community.

That's been pretty remarkable. I've had grants from CPRIT as well as other agencies like the NCI, to increase HPV vaccination rates, to increase cervical cancer screening, and colorectal cancer screening.

The metrics there have been pretty astounding. Just as an example, for colorectal cancer screening—these are all in the underserved community of Houston—we've distributed almost half a million colorectal blood test kits since 2013; 75,000 in just this past year.

We have 43,000 of those already back for testing. We sort of swamped the colonoscopy suites here in terms of those positive colorectal blood tests.

Those patients need follow-up, and the loss of follow-up rate is very, very small—less than 1 percent of those patients. We're swamping the ability of the district to do colonoscopies on all these patients. This is most certainly a result, early diagnosis of colorectal cancer, and ultimately improved outcomes, for those patients.

So, that's been a major metric of importance of CPRIT reaching out to the underserved community, increasing breast cancer screening rates, and education.

Right now we have about $30 million in CPRIT grants here at Baylor. We've benefited in terms of being able to recruit new scholars to our institution of cancer researchers.

We've particularly benefited in terms of shared resources, our core resource grants, and buying expensive equipment that have enabled us to become a major player in what's called proteomics or proteogenomics of cancer.

In terms of the prevention grants, as I mentioned, we have had a number of those that have been implemented in the underserved community. Those have been very successful as well.

When we first started CPRIT, we submitted our first cancer center core grant right about the time that CPRIT was voted positively by the Texas legislature in 2007.

We were awarded our NCI designation. Then, in 2015, we got comprehensive designation.

Obviously, we can't say that that was all due to CPRIT, but I think a lot of it was, in terms of more rapidly expanding our cancer center and its research and outreach education programs.

In terms of the state, when we started CPRIT, only MD Anderson was a Comprehensive Cancer Center. Now, there are two others: Baylor and UT Southwestern.

I would hope they would continue some of the same programs that they've had that have been successful. Particularly, the recruitment awards and the core resource awards. Those have been extremely helpful to us, and those are funding mechanisms that are difficult to get from other agencies like the federal government.

NCI, doesn't have large instrumentation grants. We've been very successful in leveraging our CPRIT awards to get those.

The individual investigator awards have been helpful, too. The return on the investment on those has been pretty astounding. That is, people who get funded, and then later on get follow-up funding from other agencies like the federal government, have been very successful.

I'm hopeful that those kinds of things will continue to evolve as well.

I think the prevention grants have to continue, because of the success that we've demonstrated not only in the Houston region, but also in the entire state.

THE CANCER LETTER | MARCH 22, 2019 | VOL 45 | ISSUE 12

Carlos Arteaga
Member, Clinical Trials Advisory Committee, CPRIT;
Director, Harold C. Simmons Comprehensive Cancer Center

> We are not assuming that this is going to be an eternal lifeline. Again, it's upon others to decide that. Our job is to make sure that this wonderful initiative, three billion dollars over ten years, is used to the best of the benefit of the citizens of the state.

The cancer center that I lead has received many grants from CPRIT—recruitment awards, individual investigator awards, multi-investigator grants, prevention grants.

Without CPRIT, it would be harder for us—harder, but not impossible—to recruit at the level of intensity that I think we are recruiting.

From talking to people from the outside, [there is a] notion that we can provide significant catalytic resources from junior, mid-level, or senior faculty that come to Texas, from the Northeast, from California, from other parts of the country.

I think it is a nice inducement, or incentive, that makes our job of recruitment easier.

Also, CPRIT provides significant support for cancer screening and prevention grants. CPRIT adds a lot of value to our ability, for our cancer mission. I think we would still be able to do it, but it would be harder to do without CPRIT.

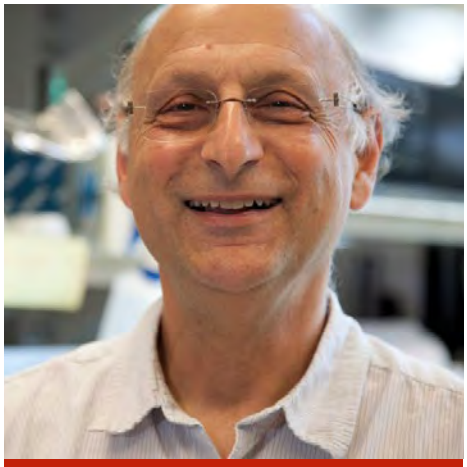
It is upon the Texas legislature to discuss the reauthorization. Our job is not to lobby for it, but to be the best stewards of this money, so patients, citizens, in Texas benefit.

On the other hand, we recognize CPRIT is just one of many possible sources of support. I think that we are committed also to the diversification of our funding, and CPRIT is one source, one important source of that, but not the only one.

I would also add that there is a number of companies that have been created as a result of the research that CPRIT has supported—these are companies that are in the process of generating new drugs for cancer that may one day be approved and improve the lives and prolong the lives or improve the quality of life of patients with cancer.

We are not assuming that this is going to be an eternal lifeline.

Again, it's upon others to decide that. Our job is to make sure that this wonderful initiative, $3 billion over ten years, is used to the best of the benefit of the citizens of the state.



Richard Kolodner
Chair, Scientific Review Council, CPRIT;
Director, Ludwig Institute for Cancer Research San Diego Branch;
Distinguished Professor, Department of Cellular and Molecular Medicine, University of California San Diego School of Medicine

> It goes beyond just competing for funds, because if you bring the right researchers, you bring in the right research programs and you can make different kinds of impact on the research that's being done in Texas.

I think that CPRIT's recruitment program is an extremely useful way to invest funds. Because, if you're able to recruit really good people to Texas, you expand the expertise, shall we say, the scientific portfolio of Texas.

If you do a good job of that, you also expand the ability of the people of Texas as an aggregate to compete for increased proportion of research funds provided by the NIH and other institutions that fund research.

It goes beyond just competing for funds, because if you bring the right researchers, you bring in the right research programs, and you can make different kinds of impact on the research that's being done in Texas, and, really, the downstream application is that these ultimately develop therapeutics or start companies that contribute to the economy, or otherwise just expanding the capabilities.

There's no institution or no state, probably, that has a monopoly, or has representation of all the types of expertise and methodologies and instrumentation that one needs to do science in the modern age.

I have always been very positive about CPRIT and that's why, when there was this moment when some people got upset—well, I think probably everybody got distressed about things—and some people sort of terminated their involvement, but for all of us in science, there's sort of a public service element.

For many in this field, we devote some fraction of our time to public service rather than just doing one's own research. And I do think that people have a certain limit to how long they're going to do any one such thing, and at some point they'll look for another project or another committee.

So, I think that some people, while it may look like they left the program in the moment of turmoil, they had really put in the length of time they were going to put in, and they were going to move onto other things. Some people stayed, and some new people were recruited, and I think that process of turnover in the scientific review board is really a good thing.

New personalities, new expertise, new ideas on a committee like that, I think, really, is helpful to the program, because of new opinions about what's important.

So, I think that the evolution of this has been extremely positive, and the people that are currently on the committee are extremely positive about the program.

I spend most of my time on the recruitment side of it, and I think that people there see that the recruitment program is extremely competitive, and the people that are being offered funding through that program are extremely high-quality. And there is something very satisfying about providing research funds to really high-quality people and programs.

On the grant side, which I'm a little bit less directly connected with, because the committee members each run a review panel, and then the review panel has a bunch of individual members on it, I mostly provide guidance for the committee members that are running the different review panels, so I'm not as intimately connected to the review of the individual grants.

But, one thing that I like from the days that I ran one of those panels was that I was able to recruit onto my review panel the kinds of people who were of the stature and intellect of the kinds of people that I would like to see reviewing my own grants.

I think there was an ability, certainly for me and hopefully that continues, to really produce a really high quality group of reviewers, and I think that there was probably more flexibility in doing that than might exist in research funding enterprises.

I was certainly extremely positive about the kind of people that I could get on my review panel. I would have loved to have them review my own grants, not because they were my friends, but because of the quality of their intellect and their scientific abilities.

Q & A

Willson spoke with
Matthew Ong and Claire Dietz,
reporters with
The Cancer Letter.

THE CANCER LETTER | MARCH 22, 2019 | VOL 45 | ISSUE 12

CONVERSATION WITH THE CANCER LETTER

James Willson: CPRIT is money well spent

> CPRIT has added about $720 million to Texas's gross product and, in addition to this, CPRIT's investment has created annual employment of over 10,000 new jobs. Those two specific things speak to the way that these investments have really worked for Texas.

James Willson
Chief scientific officer, Cancer Prevention and Research Institute of Texas

Advocates of renewing the Cancer Prevention and Research Institute of Texas argue that the agency is a good investment for the state.

"CPRIT has added about $720 million to Texas' gross product [in 2018] and, in addition to this, CPRIT's investment has created annual employment of over 10,000 new jobs," James Willson, chief scientific officer at CPRIT, said to The Cancer Letter.

A 2018 report commissioned by the institute attempted to estimate the cost of cancer and CPRIT's impact on Texas economy. The cost of cancer in Texas was estimated to be $40.3 billion in 2018, with total economic losses, including spinoff effects, of an estimated $104.6 billion in output and 1,064,595 jobs.

Total annual impact of CPRIT on Texas business activity was estimated at $22.3 billion in annual spending, $12.4 billion in output each year, and 110,265 jobs in 2018.

"I'd also point out that in addition to the commitments of about $2 billion to date, what we call follow-on funds to the two research programs, that is the research and then our commercialization and product development, has brought in an addition $2.7 billion," Willson said. "So, tangible evidence of economic impact in addition to new dollars coming into the state have been seen."

Willson spoke with Matthew Ong and Claire Dietz, reporters with The Cancer Letter.

The Cancer Letter: Can you describe your role at CPRIT as chief scientific officer?

James Willson: My role is responsibility for the research program: the development of RFA announcements for grant opportunities, and then to interact with Richard Kolodner, chair of CPRIT's Scientific Review Council, and the team that he's built in the review of those applications.

And then, once they're reviewed, to align the recommendations from our Scientific Review Council with our budget and to recommend to CPRIT'S Oversight Committee, the slate of awards.

We also monitor the progress of the awards over a period of four to five years that they are active.

It sounds like there is a lot of momentum right now in the Texas legislature in terms of reauthorizing CPRIT. Do you think CPRIT is going to get what CPRIT needs?

JW: It's very gratifying to hear from the state leadership, both the recognition of what CPRIT has accomplished and, in addition, the understanding of what's ahead of us in terms of continued opportunity to make an impact in cancer in Texas.

That leads us to be quite optimistic about the future continuation of this investment.

What are you hoping for if CPRIT were to be reauthorized?

JW: Well, at some point in time, and hopefully this year, but it may require an additional couple of years, [the hope is for] a full reauthorization of the CPRIT agency.

That would entail a commitment of $3 billion over a period of ten years.

How would you describe CPRIT's track record so far since its founding? What's the biggest impact, and how has Texas benefited from CPRIT funding?

JW: I come at this both from my role as chief scientific officer and, prior to coming on board at CPRIT, I was at UT Southwestern, and from both perspectives, what we have experienced is an investment in the capacity to do outstanding cancer research both through recruitments—people like Carlos Arteaga, the current cancer center director at UT Southwestern, for example—as well as investments in infrastructure through support of core facilities.

At UT Southwestern, this accelerated our ability to go from a very modest cancer research footprint to NCI Comprehensive Cancer Center designation in an accelerated time frame.

You probably learned from Kent Osborne, director of the Duncan Cancer Center at Baylor College of Medicine, who shared the same experience at Baylor, where CPRIT investments accelerated the Baylor cancer center's development as an NCI Designated Comprehensive Cancer Center.

CPRIT is, of course, well known for research projects that have been funded, but what are some of the most important prevention efforts that have been funded by CPRIT?

JW: The prevention efforts, actually, are in two areas.

CPRIT has created a cancer consortium across the state to build knowledge and share how to improve both early detection, as well as, prevention of hepatocellular cancer, which has accelerated both nationally and particularly in Texas.

We're quite proud of the impact that research award has made. In addition, CPRIT has invested 10 percent of the funding resources to date in prevention services across the state.

And these have had a very palpable impact on diseases like colon and breast cancer early detection, uptake in HPV vaccination, accelerating cigarette smoking abatement, and early detection of lung cancer, to name a few.

And then, more recently, an investment in expanding the access of these prevention services into rural communities of Texas.

Could you describe the economic impact that CPRIT has had since its founding?

JW: CPRIT has added about $720 million to Texas's gross product and, in addition to this, CPRIT's investment has created annual employment of over 10,000 new jobs. Those two specific things speak to the way that these investments have really worked for Texas.

I'd also point out that in addition to the commitments of about $2 billion to date, what we call follow-on funds to the two research programs, that is the research and then our commercialization and product development, has brought in an addition $2.7 billion.

So, tangible evidence of economic impact in addition to new dollars coming into the state have been seen.

Without CPRIT where would Texas be today in terms of having world-class talent in oncology?

JW: Well, Texas would have 170 fewer cancer researchers of the highest caliber, including James Allison, who as you recognize is...

A Nobel Prize winner.

JW: Both a Nobel Prize winner, but also here, by his own statements, because of a CPRIT program.

As I also indicated, UT Southwestern and Baylor were both outstanding research institutions.

What CPRIT did was to provide the motivation and catalyst to bring a focus to cancer and so both of those institutions have not only achieved NCI Comprehensive Cancer Center designation, but are contributing to and fundamentally accelerating the progress in learning opportunities to understand cancer and to mitigate it.

Right, and it's probably fair to say that there's nothing quite like CPRIT at the state level elsewhere. Would you say other states should consider funding cancer research the way Texas is funding CPRIT?

JW: Absolutely. I think that it's been very significant, and it points to a couple of things.

I think other states could take on similar types of issues with this kind of approach that are state-centered.

In addition, the secret to CPRIT's success has been the reliance on expert review panels made up of non-Texans to review the grants and a commitment of the CPRIT leadership to follow their recommendations.

This is a model that other states considering funding cancer research should follow, as it dramatically improves the integrity of the review process.

How do you anticipate CPRIT growing and developing past 2023, provided that the legislation goes through?

JW: There are enormous opportunities in front of us, not to lose sight of the fact that what CPRIT's investing in is the very best cancer research ideas, and so they'll always be at the top of the list.

But there are some areas that represent significant opportunities going forward, including our investment in childhood cancer.

To date, CPRIT has invested about 12 percent of its research awards in childhood cancer.

You recognize that as considerably higher than the federal NCI's commitment. I think that continues to be an opportunity for Texas to not only invest in, but to also make real contributions to fighting childhood cancer.

I mentioned UT Southwestern and Baylor becoming the second and third NCI–designated Cancer Centers in Texas.

I'm imagining that with another investment by CPRIT there will be institutions that are poised to become NCI–designated Cancer Centers.

UT Health San Antonio, for example, is building their cancer program with significant CPRIT funding.

Since you mentioned childhood cancer, we've been writing quite a bit about the federal budget for childhood cancer research. As you know, the president's budget proposal suggests a significant cut to NCI. Many people believe that these cuts will not go through, but if it is enacted, what does this mean for federal funding for childhood cancer?

JW: Well, we greatly appreciate the focus on childhood cancer, because I think it's not only important, but poised to be a good investment.

It's still a relatively small amount—$50 million a year is being proposed [for childhood cancer research over 10 years in the White House budget request for fiscal year 2020].

What's being suggested as a decrease in the NCI budget is devastating.

I'd like to come back to opportunities in front of us to also mention that one of the areas that we've been working hard to identify is how to accelerate the bringing of discoveries from our academic institutions into the commercialization space.

We've had several initiatives that are really designed to try to, if you will, catalyze good ideas at the academic sites to build resources for the area that's known as the Valley of Death for new drug and instrument development and invest in these so that these good ideas stay in Texas as new companies.

To date, CPRIT investments have started, expanded or brought to Texas 34 cancer-focused biotech companies.

What are the next steps for CPRIT? What can we expect in terms of the timeline for this legislature?

JW: Well, that's really up to the legislature.

We're most likely going to be called to testify in House Public Health Committee when Chairman Zerwas lays out HJR 12 and HB 39.

We have testified to Senate Finance and to the House Appropriations Committee on our Legislative Appropriations Request, which is asking for $164 million in general revenue as a stop–gap measure to prevent our funding from going on the downward curve in the next two years.

As far as the legislature, I think our next step is most likely to be called to the House Public Health Committee to talk about Chairman Zerwas' legislation.

> "The secret to CPRIT's success has been the reliance on expert review panels made up of non-Texans to review the grants and a commitment of the CPRIT leadership to follow their recommendations. This is a model that other states considering funding cancer research should follow, as it dramatically improves the integrity of the review process."

EL PASO INC.

TTUHSC El Paso: Tackling diabetes, cancer

TTUHSC El Paso Mar 29, 2019

TTUHSC El Paso Biomedical Science Professor David P. Cistola, M.D., Ph.D., is working to develop a blood test to detect metabolic changes before Type 2 diabetes sets in.

Photo provided by Texas Tech University Health Sciences Center El Paso

Location is everything. It's a truism that applies not only to real estate, but also to biomedical research. Located along the U.S.-Mexico border, Texas Tech University Health Sciences Center El Paso provides an early glimpse of what our nation will resemble.

In El Paso, over 82 percent of the population is of Hispanic descent. This demographic faces high incidences of diseases such as diabetes, breast and colon cancer, and Alzheimer's disease.

For this reason, it is vital to study the genetic and environmental influences affecting the health of our Hispanic population.

Physicians and students at the Paul L. Foster School of Medicine focus on understanding the fundamentals of diseases that impact not only Latinos, but all members of the community, as well as translating research findings into preventive measures and effective treatments.

At the Graduate School of Biomedical Sciences, our faculty train the next generation of biomedical researchers.

Below are a few examples of how TTUHSC El Paso is making a difference in biomedical research.

Preventing diabetes

Researchers led by biomedical sciences professor Dr. David P. Cistola have discovered a blood biomarker that could identify individuals at risk for Type 2 diabetes. The biomarker can be measured with a simple test using a single drop of blood.

Cistola's research aims to develop a blood test that will allow physicians to detect metabolic changes in patients at the earliest stages, giving them a chance to make lifestyle changes or initiate therapies to prevent Type 2 diabetes.

His research is funded by a two-year, $229,500 grant from the National Institutes of Health.

Taking aim at obesity-related cancer

Assistant Professor Jennifer Salinas, Ph.D., has been awarded a three-year, $1.2 million grant from the Cancer Prevention and Research Institute of Texas to fund an obesity-related cancer prevention program in El Paso. Almost 70 percent of El Paso County residents are considered overweight or obese, putting them at risk for obesity-related cancers.

Salinas' Pasos Para Prevenir Cancer program combines lifestyle education and physical activities to help participants achieve healthy weights and lessen their cancer risk.

Extending health care reach

Texas Tech El Paso is making a push into telemedicine and long-distance health education thanks to two Department of Agriculture grants.

In 2016, the Gayle Greve Hunt School of Nursing received a $430,780 grant to provide long-distance health education to underserved communities in rural West Texas.

Penny Stout, D.N.P., R.N., assistant dean and chair of the school's graduate programs, said the money from the USDA's Rural Utilities Service program, along with matching funds from the Texas Tech El Paso health sciences center, paid for video communications equipment installed in nine rural locations in West Texas.

The Paul L. Foster School of Medicine recently received a similar USDA grant of $499,227.

The goal is to improve health care for West Texas rural communities by providing access to medical specialists through the telemedicine network developed by the Gayle Greve nursing school, according to Ogechika Alozie, M.D., M.P.H., the project's principal investigator and TTUHSC El Paso's chief medical informatics officer.

Caller Times
PART OF THE USA TODAY NETWORK

OPINION

A cancer survivor's plea to the Texas Legislature: Keep funding the research

Rebecca Esparza, American Cancer Society Cancer Action Network Published 4:45 p.m. CT April 1, 2019 | Updated 7:00 a.m. CT April 2, 2019

I've had cancer twice in my life. My first diagnosis was in 2001 at age 30 and I have never been more thankful for the progress being made in the fight against cancer. Cancer research is the main reason I am a 17-year survivor of ovarian cancer, which is also why I want to see the Texas Legislature ensure that funding is authorized to continue the Cancer Prevention and Research Institute of Texas, commonly known as CPRIT.

I am deeply saddened that CPRIT funding is in jeopardy. Unless our elected officials authorize House Joint Resolution 12, the program will sunset in 2021. If the program goes away, it could jeopardize years of progress we have made to find cures and treatments. The Legislature also need to give Texans the chance to vote in November and decide whether the state should authorize an additional $3 billion in bonds to fund this program for another 10 years.

In 2007, I worked tirelessly alongside other cancer advocates with the American Cancer Society Cancer Action Network to spread the word about CPRIT to my fellow Texans. We canvassed neighborhoods, we put up signs all over town, we talked to our legislators and we networked like our lives depended on it. As a cancer survivor, my life really did depend on it. And, the lives of my family members depended on it as well given that nearly 25 percent of ovarian cancer is caused by a genetic predisposition.

When I learned 62 percent of Texas voters supported funding authorization for this program, I was never prouder to be a Texan.

Since that vote, CPRIT has funded 1,257 awards for cancer research, product development and prevention. Each year, the program has awarded up to $300 million in grant funding with 90 percent used for cancer research and up to 10 percent for cancer prevention. More than 4 million clinical services occurred in every single Texas county because of CPRIT.

Texas has set an extraordinary example for other states across the country. The truly amazing research that has been funded thanks to CPRIT includes work by 2018 Nobel Prize winner James Allison, a native of Alice, Texas, which is just 45 minutes from my own hometown of Corpus Christi.

I'll never forget the day I awoke from my six-hour surgery to see my parents softly weeping at my bedside. That night, I not only learned I had ovarian cancer but also that I would never have kids. The room was dimly lit, but I could see them holding each other up at the foot of my bed. I could see the fear in their eyes as they faced the reality that they could outlive their own child. This is a moment that I never want to see repeated in Texas or anywhere else.

Keeping CPRIT fully funded will save lives across our state and our country. It will prevent other young women from suffering the same fate as me. I implore our Texas lawmakers to pass legislation that will ensure CPRIT continues its mission to foster breakthroughs in cancer research and prevention.

My life depends on it. I've made it 17 years and I hope that is just the beginning.

Statesman

State panel OKs referendum plan for more CPRIT funding

By Bob Sechler
Follow
Posted Apr 3, 2019 at 10:07 PM
Updated Apr 4, 2019 at 6:52 PM

Texas voters might be asked this November to decide if the state should continue its major role in bankrolling the battle against cancer, after a panel of lawmakers approved a measure calling for a referendum on the question.

House Joint Resolution 12 -- setting a Nov. 5 statewide vote to authorize the state's cancer-fighting agency to issue another $3 billion in taxpayer-funded grants for cancer research and prevention -- now advances to the full state House following a green light from the Committee on Public Health.

"We have been able to help women who would have no other access to life-saving (cancer) screenings," Bernice Joseph, chief operating officer of the Rose, a health care nonprofit in Houston, told committee members. "I urge you to support this critical funding."

Joseph, whose organization has received state grants for cancer prevention, was among a handful of advocates who turned out for a public hearing Wednesday over the joint resolution, urging continued backing -- and replenished taxpayer funding -- for the Cancer Prevention and Research Institute of Texas. The anti-cancer agency, commonly known as CPRIT, was created in the wake of a statewide referendum in 2007, when Texas voters initially approved $3 billion in taxpayer-backed bonds, in increments of up to $300 million a year, to pay "for research in Texas to find the causes of and cures for cancer."

That money now is running low, however, and CPRIT has estimated it only has enough funding authority left to last the next couple of fiscal years, setting the stage for a debate over its fate. Since the 2007 referendum, Texas has become the second-largest source of public money for cancer research, trailing only the federal government.

"We must keep our foot on the pedal and continue moving forward with funding (for) CPRIT," said David Arthur, chief executive of Salarius Pharmaceuticals. He told committee members that he relocated his company to Houston from the East Coast three years ago after receiving nearly $19 million in CPRIT grants.

Arthur and others who testified, including a representative from the Texas Association of Business, said CPRIT and its grants have been a boon to the state's economy, creating jobs and making Texas a magnet for biotech companies. A cancer survivor and patient advocate also spoke, crediting CPRIT with boosting research that has led to innovative and life-saving cancer treatments.

Still, the price tag for the undertaking has been significant, with annual debt service on previously issued CPRIT-related bonds estimated to cost the state $120.6 million in the current fiscal year alone, according to the agency.

No one testified against the measure that would put the issue of additional taxpayer funding to a statewide vote. But state Sen. Charles Schwertner, R-Georgetown, has previously questioned the expense of the anti-cancer effort, calling it "noble" but non-essential as a function of state government, given numerous other demands for taxpayer money. Schwertner has filed a bill this session -- Senate Bill 200 -- that would require CPRIT to devise a path to self-sufficiency without additional taxpayer money, but it hasn't garnered a Senate committee hearing yet.

State Rep. John Zerwas, R-Richmond, sponsored HJR 12 and told members of the public health committee on Wednesday that those who turned out to testify in favor of it represent "just a sampling of the great success the state of Texas has realized in making this investment."

Among other benchmarks, CPRIT says the taxpayer funding has lured 170 researchers and their labs to the state -- including James Allison at the University of Texas MD Anderson Cancer Center, who won the 2018 Nobel Prize for his work -- in addition to spurring 109 clinical trials and triggering $1.75 billion in follow-on investing by venture capital firms in startup companies seeded with agency grants.

TribTalk

The new driving force of the Texas economy

By Tom Kowalski, President and CEO, Texas Healthcare and Bioscience Institute, April 16, 2019

Texas is an energy state. Blessed with a wealth of energy resources, including natural gas, wind and solar, Texas is an integral part of our national drive toward becoming a net energy exporter by 2020.

But energy isn't alone in driving Texas forward. We also have a burgeoning life sciences industry that — with the right policies and strategic investments — is poised to be a driving force in the Texas economy for decades to come.

What comprises the "life sciences" industry, however, is not as readily visible as the wind turbines and solar fields that dot the Texas landscape. The life sciences work is done behind closed doors in clean rooms, R&D facilities, laboratories and clinics across the state. That's where research is conducted and products are developed that help diagnose and treat disease or injury.

A burgeoning life sciences industry fosters a spirit of innovation that brings cures to patients, inspires entrepreneurship and bolsters local economies. And while our industry in Texas is robust, it has not reached its full potential; it has faced challenges due to regulation and polices that limit the scope, reach and accessibility of our innovations.

The life sciences industry is good for the Texas economy. We contribute more than $3 billion in state and federal taxes annually. Our economic output is $61.5 billion and the average salary in our industry is $110,000. The pharmaceutical sector alone indirectly supports more than 228,000 Texas jobs. There are also many indirect economic benefits.

Texas has a robust ecosystem of higher education institutions, which plays a critical role in attracting talent and producing research and development that help contribute to the industry. Investments in higher education are critical to future growth. So are efforts such as the Governor's University Research Initiative, launched by Gov. Greg Abbott, which helps attract and recruit top researchers to Texas schools. Industry clusters that grow out of academia help incubate ideas and create an ecosystem of suppliers, businesses and associated industries that continue to contribute to the economy.

The life sciences also drive innovation. Pharmaceutical firms with operations in Texas are making breakthroughs in areas such as oncology, ophthalmology and stem cell therapies. These firms have manufacturing, research and development, and corporate headquarters in our state — drawn here by a talented workforce and a pro-business environment that helps cultivate innovation and drive growth.

Medical device companies in Texas are also on the cutting edge, crafting new healthcare solutions in specialties from cardiology to orthopedics. Clinical trials are another little-known aspect of the industry that drives innovation. Texas has 25,000 trials currently underway, the third most in the U.S., bringing both clinical and economic value to the state. More clinical trials mean that more Texans have access to experimental therapies.

Which brings us to the most important value the life sciences industry provides to Texas.

A strong and growing life sciences industry is important to the people of Texas. Creating an environment that attracts new firms, research and innovation only serves to bring the newest life-saving discoveries to patients.

Patients benefit tremendously from the research, programs and services associated with the Cancer Prevention and Research Institute of Texas (CPRIT). In 2007, the voters authorized the issuance of $3 billion in bonds over 10 years to fund grants for cancer-related academic research and product development. To date, CPRIT has awarded 1,321 grants totaling more than $2.17 billion. CPRIT's funding has had numerous direct and indirect impacts across the state.

Texas is primed to grow this key industry sector, and strong public policy and action by our state Legislature is critical to supporting it. The path is twofold: Texas policymakers need to advance strong public health policies that promote lifesaving discoveries like vaccines, and champion those that defend patient access to cures. Without attention to the practices of players within the drug supply chain that drive up costs for patients, prohibitions on stem cell research, and limits to innovative medications in Medicaid, life sciences in Texas will only remain at a status quo.

Our philosophy is this: if it doesn't extend lives; if it doesn't promote access to cures; if it limits the scope of discovery; it's not good policy. We hope Texas lawmakers follow this advice.

Tom Kowalski is the President & CEO of the Texas Healthcare & Bioscience Institute (THBI). The 2019 report on the life sciences industry can be found online.

TEXAS POLITICS

Texas House approves bills to secure future of cancer research agency

by: Steffi Lee

Posted: Apr 16, 2019 / 09:43 AM CDT / Updated: Apr 16, 2019 / 07:31 PM CDT

AUSTIN (Nexstar) — Lawmakers in the Texas House have approved two bills that could determine the future of the Cancer Prevention and Research Institute of Texas.

Texas voters approved a constitutional amendment more than a decade ago to establish the program, also known as CPRIT. It allowed the state to issue $3 billion in bonds to fund cancer research and prevention programs throughout the state.

Without further action from the legislature, the agency will sunset in 2023. However, Rep. John Zerwas, a Richmond Republican, filed two bills this legislative session to renew the agency.

House Bill 39 will allow CPRIT to continue beyond the original timeframe set by the initial acting legislation. House Joint Resolution 12 proposes a constitutional amendment authorizing the legislature to increase the maximum bond amount authorized for CPRIT to $6 billion.

"So much has yet to come and that needs to come over the next decade of research and investments and various cures and preventions for cancer," Zerwas said.

Zerwas praised the work that's already taking place in Texas.

"I really see us as being at the forefront of cancer research, which should translate into cures and certainly preventative measures," he said.

For two-time cancer survivor Rebecca Esparza, the possibility of CPRIT's renewal gives her a glimpse of hope. She helped rally for CPRIT's creation back in 2007.

"My doctors at MD Anderson told me that my likelihood of getting cancer again in the future is really high," she said. "I'm counting on research to save my life."

Esparza, who was diagnosed with both ovarian cancer and thyroid cancer, received the news about her diagnoses before she was the age of 40. In 2016, she also underwent a 12-hour surgery when doctors thought she had colon cancer. Managing the side effects are part of Esparza's daily life.

Rebecca Esparza helped rally for CPRIT's creation in 2007. (Courtesy: Rebecca Esparza)

"When I was diagnosed in 2001, [doctors] said I had about eight months to live," Esparza said.

"I was given a really bitter, bitter set of lemons that I've been able to make some pretty sweet lemonade out of," she said. "I can still have a voice. I can share that voice and I can still have some sort of an influence on where we go from here."

According to CPRIT's website, the agency has funded 1,371 awards for cancer research, product development and prevention since 2010. The total amount awarded so far is $2,260,400,194. Recipients include academic institutions, non-profits and private companies, according to the agency.

The Texas Senate will have to approve these bills in order for them to head to the Governor.

"I actually think both chambers are going to agree on this," Zerwas said. "The Senate has taken some action already and in fact, we're going to meet it up together and we'll figure it out. It doesn't matter whose name is on the bill. It just matters that it happens."

Austin American-Statesman

Opinion

Keep Texas at the forefront of the fight against cancer

BUY PHOTO ▲ HIDE CAPTION

In 2007, cancer survivors and supporters joined the thousands running and walking in the Livestrong Challenge 5K in Austin to support the fight against cancer and a proposal to create the Cancer Prevention and Research Institute of Texas. [RALPH BARRERA/AMERICAN-STATESMAN/FILE]

By Jeff Garvey and Amelie Ramirez

Posted Apr 28, 2019 at 9:43 AM

Updated Apr 28, 2019 at 9:44 AM

Today, there are more than 775,000 cancer survivors living in Texas, according to the 2018 Texas Cancer Registry. These Texans owe their lives to the incredible advancements in treatments for cancer – many of which have been fueled by biomedical research funded by the Cancer Research and Prevention Institute of Texas (CPRIT).

In 2007, the people of Texas voted overwhelmingly in favor of creating this agency charged with investing $3 billion in cancer research and prevention over 10 years. Today, CPRIT ranks as the nation's second-largest government funder of cancer research behind the National Cancer Institute.

But Texas' future leadership in the cancer fight is at risk of being lost without urgent action from the Texas legislature. Lawmakers are set to appropriate the final $436 million in voter-approved funds for CPRIT this session with no commitment of future funding for the agency beyond 2021.

If CPRIT funding disappears, 96,000 Texans won't get lifesaving prevention clinical services in 254 counties as programs are dismantled for lack of funding. Advances made for Texas to become the "Third Coast" for biotechnology and biomedical research would be set back. And Texas would lose $720 million per year in direct gross product and over 10,000 permanent high-quality jobs.

The people of Texas both need and want CPRIT to continue its work discovering breakthroughs in prevention, early detection, screening, diagnosis and treatment.

In a recent statewide survey, 89 percent of voters said it is important for Texas to remain a leader in cancer research and prevention. In addition, the poll shows strong bipartisan support for continuing state funding of CPRIT.

At the Livestrong Foundation, we feel uniquely qualified to tout CPRIT's importance to our state and the cancer cause broadly. We have supported the agency from its infancy as an idea conceived by Cathy Bonner, who served in Governor Ann Richards' cabinet. We championed the grassroots initiative spurred by patient advocates and cancer survivors. We were there when Gov. Rick Perry signed legislation setting the details for establishing CPRIT. We campaigned for Proposition 15, the landmark ballot measure put before voters on Nov. 6, 2007 authorizing the Texas Public Finance Authority to issue the bonds necessary to fund the Institute and grants. And we've been the recipients of two CPRIT grants totaling $600,000 in funding for programs benefiting people affected by cancer.

Over the past 10-plus years, we've seen how the $2.26 billion that CPRIT has invested in 1,372 of the best ideas in cancer research, product development and prevention are building a vibrant life sciences and prevention infrastructure in our state. Simply put, CPRIT has enhanced Texas' competitive edge in the global fight against cancer.

We are grateful that the Texas House of Representatives overwhelmingly passed House Joint Resolution 12 on April 16. Authored by House Appropriations Committee Chairman John Zerwas (R-Richmond), the resolution proposes a constitutional amendment authorizing the legislature to appropriate an additional $3 billion for CPRIT to be submitted to voters in the general election on Nov. 5.

We encourage the Senate to continue Texas' leadership in the fight against cancer by passing HJR 12 before the session ends on May 27. As Sen. Jane Nelson (R-Flower Mound), the lead author of the initial Senate legislation to establish CPRIT in 2007, said of the creation of the agency 12 years ago, "I don't think there's a greater legacy we can leave our children or grandchildren than providing research to cure cancer."

We agree wholeheartedly.

Cancer research transforms and saves lives, but this disease cannot be overcome working alone. It requires bipartisan collaboration and partnership. We hope the Texas legislature will allow CPRIT to continue its pioneering work in cancer research and keep Texas at the forefront of the fight against cancer.

Garvey and Ramirez are on the board of directors of the Livestrong Foundation, which has invested more than $580 million in cancer programs for patients, survivors, caregivers and their families.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER

SUBJECT: PREVENTION PROGRAM UPDATE

DATE: MAY 6, 2019

FY 2019 Cycle 2 (19.2) Prevention Applications

CPRIT released three RFAs in September 2018 for the second review cycle of FY 2019. The peer review panel will meet in Dallas on May 21-22 to evaluate the 27 FY19.2 prevention applications requesting $38,105,829 (see table below). The Prevention Review Council (PRC) will meet on July 8, 2019, to make award recommendations to the Program Integration Committee (PIC). The PIC's recommendations will be presented to the Oversight Committee in August.

FY 2019.1 (19.1) Application Data by Mechanism

Mechanism	Received	Funds Requested
Evidence-based Cancer Prevention Services	7	$ 6,844,590
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	13	$24,422,409
Tobacco Control and Lung Cancer Screening	7	$ 6,838,830
TOTAL	**27**	**$38,105,829**

FY 2020 Cycle 1 Prevention RFAs

CPRIT will release FY 2020 Cycle 1 RFAs (described below) on June 6. Applications are due September 4, 2019. The Oversight Committee will consider the recommendations at the February 2019 meeting. Dissemination mechanism applications are reviewed and recommended quarterly.

Prevention Program RFA Descriptions

- *Evidence-Based Cancer Prevention Services*
  Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.
  Award: Maximum of $1M over 36 months.

- *Tobacco Control and Lung Cancer Screening*
  Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
  Award: Maximum of $1M over 36 months.

- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
  Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
  Award: Maximum of $2M over 36 months.

- *Dissemination of CPRIT-Funded Cancer Control Interventions*
  Seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
  Award: Maximum of $300,000 over 24 months.

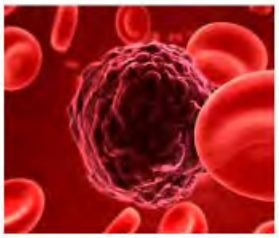
Providing Hope, Life Saving Services

Screening Outcomes as of February 2019

1,296,748 screenings/ diagnostics

363,119 people never before screened

16,274 Precursors detected



3,640 cancers detected

Providing Hope, Life Saving Services

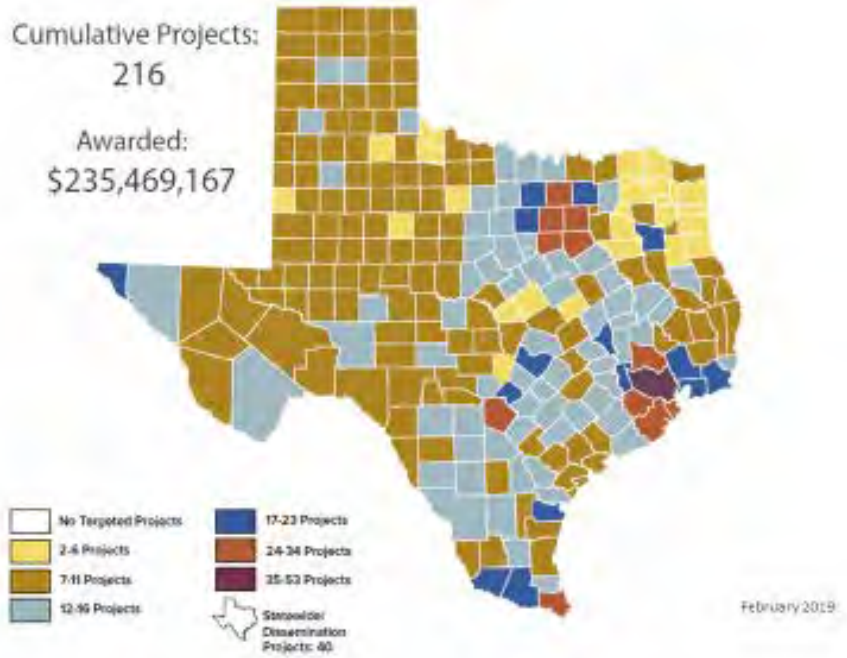
> 5.4 Million Prevention Services

2.7 M Education & Training for public and professionals

2.7 M Clinical services:

- ✓Breast, cervical, colorectal cancer screenings & diagnostics
- ✓Hepatitis B & C screening
- ✓HPV & Hepatitis B vaccinations
- ✓Tobacco cessation counseling, treatment and screening
- ✓Genetic testing
- ✓Survivor programs and services

Counties of Residence of People Served



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

4

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: CINDY WALKERPEACH, PHD
CHIEF PRODUCT DEVELOPMENT OFFICER

SUBJECT: CPRIT PRODUCT DEVELOPMENT PROGRAM UPDATE

DATE: MAY 3, 2019

Product Development Research Award Update

Product Development Research FY 2019 Cycle 1

During the Due Diligence Evaluation phase of the FY 2019 Cycle 1 review cycle, the CPRIT Product Development Review Council voted to take "No Action" on two applications, pending review of additional information requested from each applicant. The PDRC has received and reviewed requested information provided by one of the applicants and declined to move the application to diligence. The second "No Action" application remains pending.

If the PDRC recommends an award to the remaining company after reviewing the additional information, Dr. WalkerPeach will present the recommendations to the PIC and Oversight Committee for consideration at the August OC meeting.

Product Development Research FY 2019 Cycle 2

CPRIT released three RFAs for the FY 2019 Cycle 2 (19.2) cycle on December 5, 2018, and accepted applications through January 30, 2019. Companies submitted 27 proposals, which were assigned to peer reviewers for evaluation. The peer review screening calls were held on March 18 and 19, 2019 to discuss the applications and reviewers selected 11 companies to make in-person peer review presentations held in Dallas April 16-18, 2019. Four of the applications presented at the in-person peer review meeting were selected to move forward into the due diligence evaluation phase of the review process.

Review Cycle 19.2 Application Data by Mechanism

Mechanism	Applications Received	Funds Requested	Invited to In Person	Invited to Due Diligence	Funds Requested
Texas Company	4	$63.9M	3	1	$15.4M
Relocation Company	9	$108.8M	3	1	$7.4M

Seed Company	14	$37.8M	5	2	$6.0M
TOTAL	**27**	**$210.4M**	**11**	**4**	**$28.8M**

The PDRC will convene in July 2019 to consider the due diligence reports and make final award recommendations for consideration by the PIC and the Oversight Committee. Dr. WalkerPeach will present the PIC's recommendations for the 19.2 cycle awards at the August 2019 Oversight Committee meeting.

Product Development Research RFAs FY 2020 Cycle 1

The FY 2020 RFA release schedule, which the Oversight Committee approved in February 2019, follows:

- *Texas Company Product Development Research Award* (TXCO):
  RFA supporting TX based companies

This award supports early-stage and established companies in the development of innovative cancer products, services and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish ecosystem infrastructure that is critical to the development of a robust life-science industry; or must fill a treatment or research gap with a significant unmet clinical need. Companies must be currently headquartered in Texas.
Award: Up to $20 million over a maximum timeline of three years.

- *Company Relocation Product Development Award* (RELCO):
  RFA supporting companies relocating to TX

This award supports early-stage and established companies in the development of innovative cancer products, services and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish ecosystem infrastructure that is critical to the development of a robust life-science industry; or must fill a treatment or research gap with a significant unmet clinical need. Companies must relocate to Texas upon receipt of award.
Award: Up to $20 million over a maximum timeline of three years.

- *Seed Award for Product Development Research* (SEED):
  RFA supporting new company formation

The award supports very early-stage "startup" companies that are earlier in their development timeline than CPRIT's two other Product Development Awards, the Texas Company Award (TXCO) and the Company Relocation Award (RELCO). The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish ecosystem infrastructure that is critical to the development of a robust life-science

industry; or must fill a treatment or research gap with a significant unmet clinical need. Company applicants must be headquartered in Texas or be willing to relocate to Texas upon receipt of award.
Award: Up to $3 million over a maximum timeline of three years.

Product Development Research FY 2020 Cycle 1

The application portal for the 20.1 cycle is scheduled to open in June 27, 2019 and close on August 7, 2019. Awards for Cycle 20.1 round are planned to be presented to the Oversight Committee at the February 2020 meeting.

Product Development Advisory Committee Meeting

The CPRIT Product Development Advisory Committee (PDAC) is an *ad hoc* advisory committee that offers guidance to the Oversight Committee on issues related to CPRIT's Product Development Research Program. The PDAC convened on April 11, 2019 via teleconference to discuss several programmatic items. Jonathan MacQuitty, PhD, Venture Partner at Lightspeed Venture Partners and Chair of the PDAC, will present a report on the PDAC's recommendations related to the CPRIT Product Development Research Program to the Oversight Committee at the May 15, 2019 meeting.

Product Development Review Council

The CPRIT Product Development Review Council (PDRC) presides over the peer review process for CPRIT's Product Development Research Program. The PDRC critically reviews peer reviewer critiques and makes final award recommendations to CPRIT's Program Integration Committee (PIC).

- Sandra Silberman, MD, PhD, has notified CPRIT that she intends to step down from the PDRC effective May 28, 2019 due to bandwidth and health issues. Dr. Silberman has been an extremely productive PDRC member and profoundly instrumental in robustly evaluating clinical-stage applicants. We welcome her return if/when she is again available.
- The Chair (Jack Geltosky) has recommended a new PDRC member, Kelly Bolton, MD, PhD, who was previously approved as a product development peer reviewer. Dr. Bolton replaces Dr. Sandra Silberman effective June 1, 2019.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, STAFF ATTORNEY
SUBJECT:	APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE:	MAY 8, 2019

Summary and Recommendation

The Chief Executive Officer has appointed five experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires the appointments be approved by the Oversight Committee. The Nominations Subcommittee will discuss the appointments at its meeting on May 10 and vote on whether to recommend that the Oversight Committee vote to approve the appointments.

Discussion

Scientific Research and Prevention Programs committee members (also referred to as "peer reviewers") are responsible for reviewing grant applications and recommending grant awards for meritorious projects addressing cancer prevention and research, including product development research. Peer reviewers perform an important role for the state; all CPRIT grant awards must first be recommended by a Scientific Research and Prevention Programs committee. Individuals appointed to serve as CPRIT's Scientific Research and Prevention Programs committee members must be exceptionally qualified, highly respected, well-established members of the cancer research, product development research, and prevention communities.

Texas Health and Safety Code Section 102.151(a) directs the Chief Executive Officer to appoint members to the Scientific Research and Prevention Programs committees. The CEO's appointments are final once approved by a simple majority of the Oversight Committee. The Nominations Subcommittee charter assigns the subcommittee with the responsibility "to circulate to Oversight Committee members in advance of a public meeting written notification of the committee's intent to make the nomination, along with such information about the nominee as may be relevant."

The nominations subcommittee will review the peer reviewer appointments at its May 10th meeting.

Academic Research Peer Review Panels

- Dennis Carson, M.D.
- Eva May, MBA
- Kirk Wangensteen, M.D., Ph.D.

Product Development Research Peer Review Panels

- Jerome Zhengrong Liang, Ph.D.
- Michael Robkin, MBA

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Carson, Dennis A.

eRA COMMONS USER NAME (credential, e.g., agency login): dcarson

POSITION TITLE: Professor of Medicine, Director Emeritus, Moores Cancer Center

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Haveford College, Haveford, PA	BA	05/1966	Premed
Columbia University, New York, NY	MD	05/1970	Medicine

A. Personal Statement

I have spent my career discovering new targets, and developing therapeutics, in the fields of oncology, autoimmune and infectious diseases. After completing my internal medicine training, I received extensive post-doctoral experience in immunogenetics (M. Weigert), immunochemistry (H. Metzger) and biochemistry (J. Seegmiller). At the Scripps Clinic for 14 years, I developed the drug cladribine from bench to bedside for the effective treatment of hairy cell leukemia, as well as two approved clinical diagnostic agents, advancing to become head of the clinical immunology division. After moving to UCSD in 1990, I directed the Stein Institute for Research on Aging for 13 years, and then the Moores Cancer Center for 8 years. NIH funding for the Cancer Center more than doubled during my tenure. During this period, I also co-founded several biotechnology companies in the vaccine and oncology areas (Vical, Triangle, Dynavax, Salmedix, Samumed) that successfully developed new drugs, based upon many patents from my laboratory in the fields of DNA immunization, nucleoside analogs, and Wnt signaling. I also supervised a large development project from the California Institute for Regenerative Medicine that brought from bed to bedside, a monoclonal antibody against cancer stem cells. Currently, I direct an NIH funded contract in cancer immunotherapy drug discovery.

1. Chan M, Hayashi T, Kuy CS, Gray CS, Wu CC, Corr M, Wrasidlo W, Cottam HB, **Carson DA**. Synthesis and immunological characterization of toll-like receptor 7 agonistic conjugates. Bioconjugate chemistry. 2009; 20(6): 1194-200. PMID: 19445505 PMCID: PMC2976567
2. Sato-Kaneko F, Yao S, Ahmadi A, Zhang SS, Hosoya T, Kaneda MM, Varner JA, Pu M, Messer KS, Guiducci C, Coffman RL, Kitaura K, Matsutani T, Suzuki R, **Carson DA**, Hayashi T, Cohen EE. Combination immunotherapy with TLR agonists and checkpoint inhibitors suppresses head and neck cancer. JCI insight. 2017; 2(18). PMID: 28931759 PMCID: PMC5621908
3. Hosoya T, Sato-Kaneko F, Ahmadi A, Yao S, Lao F, Kitaura K, Matsutani T, **Carson DA**, Hayashi T. Induction of oligoclonal CD8 T cell responses against pulmonary metastatic cancer by a phospholipid-conjugated TLR7 agonist. Proc Natl Acad Sci U S A. 2018 Jul 17; 115(29):E6836-E6844. doi: 10.1073/pnas.1803281115. PMID: 29967183 PMCID: PMC6055176

B. Positions and Honors

Positions and Employment

1972 – 1974 Clinical Associate, Section on Chemical Immunology, Arthritis and Rheumatism Branch, National Institute of Arthritis, Metabolism & Digestive Disease, National Institutes of Health, Bethesda, MD
1974 – 1975 Postdoctoral Fellow, Department of Medicine, University of California, San Diego, CA
1976 – 1990 Assistant Member-Member, Department of Clinical Research, Scripps Clinic & Research Foundation, La Jolla, CA

1990 – Pres Professor of Medicine, Department of Medicine, University of California, San Diego, La Jolla, CA
1990 – 2003 Director, The Sam and Rose Stein Institute for Research on Aging, University of California, San Diego, La Jolla, CA
2003 – 2011 Director, Moores Cancer Center, University of California San Diego Medical Center, La Jolla, CA
2011 – Pres Director Emeritus, Moores Cancer Center, University of California San Diego Medical Center, La Jolla, CA

Honors and Awards
Lee C. Howley, Sr., Prize, 1987; American Academy of Arts and Sciences, 1995; Sc.D. (Hon.), University of Aix-Marseille, 1995; National Academy of Sciences, 2003; AACR-Bruce F. Cain Memorial Award, 2004; Institute of Medicine, 2005; National Academy of Inventors, 2013.

C. Contributions to Science

1. Development of cladribine. My early publications addressed the mechanism by which a genetic deficiency of adenosine deaminase (ADA) caused selective depletion of lymphocytes. We showed that in the absence of ADA, non-dividing lymphocytes could not remove deoxyadenosine, and progressively converted it to dATP, because of a uniquely high kinase/nucleotidase ratio, compared to other cell types. We predicted that deoxyadenosine analogs resistant to ADA would also show selective cytotoxicity to lymphocytes. Subsequently we synthesized and tested more than twenty deoxyadenosine analogs before selecting 2-chlorodeoxyadenosine (cladribine) for development. Together with XD Wang, we demonstrated that the triphosphate of cladribine could directly activate the APAF-depending apoptotic pathway in lymphocyte extracts. Together with the late E. Beutler, we tested cladribine in multiple clinical trials, leading to its approval as a drug of choice for hairy cell leukemia. The bench to bedside series of experiments took 13 years to complete, years before targeted therapy became a focus of cancer research.

a) **Carson DA**, Kaye J, Seegmiller JE. Lymphospecific toxicity in adenosine deaminase deficiency and purine nucleoside phosphorylase deficiency: possible role of nucleoside kinase(s). Proc Natl Acad Sci U S A. 1977 Dec;74(12):5677-81. PMID: 202960; PMCID: PMC431856.
b) **Carson DA**, Wasson DB, Beutler E. Antileukemic and immunosuppressive activity of 2-chloro-2'-deoxyadenosine. Proc Natl Acad Sci U S A. 1984 Apr;81(7):2232-6. PMID: 6585795; PMC345472.
c) Piro LD, Carrera CJ, **Carson DA**, Beutler E. Lasting remissions in hairy-cell leukemia induced by a single infusion of 2-chlorodeoxyadenosine. N Engl J Med. 1990 Apr 19;322(16):1117-21. PMID: 1969613.
d) Leoni LM, Chao Q, Cottam HB, Genini D, Rosenbach M, Carrera CJ, Budihardjo I, Wang X, **Carson DA**. Induction of an apoptotic program in cell-free extracts by 2-chloro-2'-deoxyadenosine 5'-triphosphate and cytochrome c. Proc Natl Acad Sci U S A. 1998 Aug 4;95(16):9567-71. PMID: 9689121; PMC21379.

2. Discovery and therapeutic exploitation of p16 deficiency in cancer. My laboratory discovered that a large percentage of cancer cell lines and primary tumors lack the enzyme methylthioadenosine phosphorylase (MTAP), typically because of a homozygous deletion on chromosome 9p21. Subsequently, we performed positional cloning experiments which revealed the co-deletion of the closely linked p16/CDKN2 gene, which encodes a natural inhibitor of cyclin dependent kinase 4 (CDK4). We devised a synthetic lethal strategy for the selective killing of MTAP/p16 deficient cells, which entered clinical trials. The Pfizer Corporation then developed a synthetic CDK4 inhibitor, which was recently approved for the treatment of cancer.

e) Kamatani N, **Carson DA**. Abnormal regulation of methylthioadenosine and polyamine metabolism in methylthioadenosine phosphorylase-deficient human leukemic cell lines. Cancer Res. 1980 Nov;40(11):4178-82. PMID: 6781742.
f) Carrera CJ, Eddy RL, Shows TB, **Carson DA**. Assignment of the gene for methylthioadenosine phosphorylase to human chromosome 9 by mouse-human somatic cell hybridization. Proc Natl Acad Sci U S A. 1984 May;81(9):2665-8. PMID: 6425836; PMC345130.

g) Nobori T, Miura K, Wu DJ, Lois A, Takabayashi K, **Carson DA**. Deletions of the cyclin-dependent kinase-4 inhibitor gene in multiple human cancers. Nature. 1994 Apr 21;368(6473):753-6. PMID: 8152487.

3. Development of immunostimulatory DNA sequences as potent vaccine adjuvants. My laboratory was one of the first to report the effectiveness of DNA immunization, with multiple issued patents. Subsequently, my own laboratory, and that of A. Krieg, found that DNA immunization depended on the presence of potent immunostimulatory DNA sequences (ISS), that were subsequently shown to be agonists for TLR9. The ISS adjuvant that we described has been administered to more than 10,000 patients, sponsored by Dynavax, a company that I founded. FDA review of the phase 3 trial will occur in 2015-2016. Subsequently, we synthesized and tested a series of TLR7 and TLR4 agonists, and demonstrated their potency as vaccine adjuvants and as immunotherapeutics for cancer.

h) Raz E, Tighe H, Sato Y, Corr M, Dudler JA, Roman M, Swain SL, Spiegelberg HL, **Carson DA**. Preferential induction of a Th1 immune response and inhibition of specific IgE antibody formation by plasmid DNA immunization. Proc Natl Acad Sci U S A. 1996 May 14;93(10):5141-5. PMID: 8643542; PMC39421.
i) Sato Y, Roman M, Tighe H, Lee D, Corr M, Nguyen MD, Silverman GJ, Lotz M, **Carson DA**, Raz E. Immunostimulatory DNA sequences necessary for effective intradermal gene immunization. Science. 1996 Jul 19;273(5273):352-4. PMID: 8662521.
j) Wu CC, Hayashi T, Takabayashi K, Sabet M, Smee DF, Guiney DD, Cottam HB, **Carson DA**. Immunotherapeutic activity of a conjugate of a Toll-like receptor 7 ligand. Proc Natl Acad Sci U S A. 2007 Mar 6;104(10):3990-5. Epub 2007 Feb 21. PMID: 17360465; PMC1820696.

4. Discovery of cancer stem cell antigens. My laboratory reported that Wnt receptors could be targets for immunotherapy in cancer. Together with T. Kipps, we subsequently found that the Wnt receptor ROR1 was a cancer specific antigen, expressed in both leukemias and solid tumors. We developed a monoclonal antibody against ROR1 that is currently in clinical trials.

k) Rhee CS, Sen M, Lu D, Wu C, Leoni L, Rubin J, Corr M, **Carson DA**. Wnt and frizzled receptors as potential targets for immunotherapy in head and neck squamous cell carcinomas. Oncogene. 2002 Sep 26;21(43):6598-605. PMID: 12242657.
l) Fukuda T, Chen L, Endo T, Tang L, Lu D, Castro JE, Widhopf GF 2nd, Rassenti LZ, Cantwell MJ, Prussak CE, **Carson DA**, Kipps TJ. Antisera induced by infusions of autologous Ad-CD154-leukemia B cells identify ROR1 as an oncofetal antigen and receptor for Wnt5a. Proc Natl Acad Sci U S A. 2008 Feb 26;105(8):3047-52. doi: 10.1073/pnas.0712148105. Epub 2008 Feb 19. PMID: 18287027; PMC2268582.
m) Zhang S, Cui B, Lai H, Liu G, Ghia EM, Widhopf GF 2nd, Zhang Z, Wu CC, Chen L, Wu R, Schwab R, **Carson DA**, Kipps TJ. Ovarian cancer stem cells express ROR1, which can be targeted for anti-cancer-stem-cell therapy. Proc Natl Acad Sci U S A. 2014 Dec 2;111(48):17266-71. doi: 10.1073/pnas.1419599111. Epub 2014 Nov 19. PMID: 25411317; PMC4260559.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/47587740/?sort=date&direction=ascending

D. Research Support

ACTIVE

HHSN272201400051C(Carson) 09/30/2014 – 09/29/2019
Adjuvant Discovery Program
Adjuvant Discovery For Vaccines Against West Nile Virus and Influenza virus
The overall objective of this project is to identify and characterize small molecules that sustain activation of antigen presenting cells using high throughput screening methods, to select lead compounds by structure activity relationship study, to identify targets, and to verify the action in preclinical animal models in vivo.
Role: Principal Investigator

HHSN272201400051C – Modification #6 Universal Flu Vaccine Studies Expansion Change Order (Carson)
09/30/2017 – 04/30/2019
NIH/NIAID Adjuvant Discovery Program
Title: Hemagglutinin stalk-directed universal influenza virus vaccine using TLR7 and TLR4 combination adjuvants,
Major Goals: We have previously demonstrated the enhanced protective efficacy against heterologous virus challenge utilizing chimeric hemagglutinin (HA) antigens in combination with a synthetic TLR4 ligand and a lipid conjugated TLR7 ligand (Goff, Hayashi et al. 2015). With the help of supplemental funding, we are conducting studies to determine the optimal ratio and formulation of the two ligands. We tested the efficacy of formulated combined adjuvants in murine models using recombinant chimeric HA stalk virus/antigens.
To further optimize the combination adjuvant, and to bring forward toward the development stage, we aim to determine the mechanism of action and to identify possible biomarkers for protective efficacies as a TLR7 and TLR4 adjuvanted universal influenza vaccine.
Role: Principal Investigator

R44HL126285 (Wang) 07/01/2017 – 06/30/2019
NIH/NHLBI
Title: An Innovative System for Cord Blood Stem Cell Isolation
Subaward Major Goals: Animal research associated with the development an innovative microbubble-based technology for rare cell isolation in blood.
Role: Consortium PI

DISC2-09615(PI: Kaufman) 05/01/17-04/30/19
California Institute for Regenerative Medicine
Targeted off-the-shelf immunotherapy to treat refractory cancers
The goal is to use human induced pluripotent stem cells (iPSCs) to produce a novel targeted, “off-the-shelf” cellular immunology product that can be translated to clinical therapies to treat patients with relapsed/refractory cancers that do not currently have an effective treatment option.
Role: Co-Investigator

COMPLETED

R44CA176892 04/01/2015 – 03/31/2017
NIH (Subaward to UCSD)
Buoyancy-Based Bioseparations
Major Goals: The goal of the proposed work is to develop a simple, robust, and cost-efficient circulating tumor cell (CTC) isolation system based on an innovative BUBLES (BUoyancy enaBLEd Separation) technology for point-of- care applications.
Role: Subaward PI

HHSN272201400051C-Supplement (Carson) 09/30/2016 – 09/29/2017
Adjuvant Discovery Program
Formulation of a TLR7 and TLR4 adjuvant for hemagglutinin stalk-mediated universal influenza virus vaccine
Major Goals: The goal of this project is to optimize a TLR4 and TLR7 adjuvanted vaccine formulation for a universal influenza vaccine. This project is a part of the NIAID-supported, UCSD Adjuvant Discovery Program. We propose to discover the compounds that enhance the TLR4 adjuvants in the current adjuvant discovery contract proposal.
Role on Project: Principal Investigator

U54 CA132379 09/28/2015-08/31/2018
NIH
SDSU/UCSD Cancer Center Comprehensive Partnership (Project 1)

Major Goals: The goal of the application is to seek funding to continue to support the SDSU/UCSD Comprehensive Cancer Center Partnership in order to continue to develop outstanding programs in research, research education, and community outreach to understand causes for cancer health disparities and to reduce the burden of cancer among Hispanic/Latino communities in our catchment areas of San Diego and Imperial counties.
Role: Co-Investigator

HHSN272201400051C-Supplement (Carson) 09/30/2015 – 09/29/2018
Adjuvant Discovery Program
A TLR7 and TLR4 adjuvanted hemagglutinin stalk-directed universal influenza virus vaccine
Major Goals: We intend to optimize small molecule TLR7 and TLR4 agonists for adjuvants in a universal influenza vaccine. Furthermore, we will compare combinations of innate immune receptor agonists to improve the adjuvant efficacies of the universal vaccine.
Role on Project: Principal Investigator

7005-14 (Kipps) 10/01/2013 – 10/30/2018
Leukemia and Lymphoma Society
Specialized Center of Research Program
Specific Targets for Therapy of Patients with Chronic Lymphocytic Leukemia
The overall goal is to develop novel and specific forms of treatment that could be curative on their own or complement the activity of other agents that are less specific for CLL.
Project 3: Pharmacologic Inhibition of Wnt Signaling in Chronic Lymphocytic Leukemia
Role: Project 3 Leader

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: May, Eva A.

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Patient-Powered Health and Research Advocate

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of North Carolina – Chapel Hill	BA	12/1978	English
Columbia University, New York, NY	MBA	08/1980	Marketing and Finance
Stanford Online – Patient Engagement Design		11/2014	Healthcare
RiceX – Medicine in the Digital Age		11/2014	Healthcare
GeorgetownX – Genomic Medicine Gets Personal		12/2014	Healthcare
University of TorontoX – Behavioural Economics in Action		12/2014	Behavioral Economics
Darden (Coursera) – Design Thinking for Business Innovation		03/2015	Patient/Human-Centered Design
Duke (Coursera) – Data Analysis and Statistical Inference		05/2015	Healthcare
HarvardX - Innovating in Health Care		08/2015	Healthcare
+Acumen Courses in partnership with IDEO.org – Design Kit and Design Kit: Prototyping		03/2016	Patient/Human-Centered Design
FORCE (Facing Our Risk of Cancer Empowered) - Online		11/2016	Patient Research Advocacy – Breast Cancer
CITI Training (Duke University) - online		06/2017	GCP for Clinical Trials with Investigational Drugs and Medical Devices
Cochrane Online Course: Understanding Evidence-Based Healthcare: A Foundation for Action		06/2017	Healthcare
NBCC Project LEAD Institute – La Jolla, CA		07/2017	Intensive Science Course for Breast Cancer Advocates
Protecting Human Research Participants - NIH		02/2018	Clinical Trials
Scientist <--> Survivor			

A. Personal Statement

Eva May is an entrepreneurial leader with a passion for meaningful participation in the paradigm shift to patient-powered research and personalized healthcare for all. Prior to her immersion in translational research, Eva was the founder of a national advertising agency, developing successful consumer-centered marketing programs across multiple cultures. In 2008, Eva was diagnosed with Stage 1 breast cancer and subsequently learned that she carries a BRCA2 mutation. Her personal breast cancer journey opened her eyes to the world of translational research, and her interest was strong enough that she closed her successful advertising agency and moved to South Dakota to join the leadership team of a startup breast cancer research organization seeded with a $100M gift. She thoroughly embraced the opportunity to regularly interact with scientists and clinicians involved in breast cancer research and treatment, and to personally witness the promise of precision medicine, research and discoveries. Since 2014, Eva has dedicated herself to becoming a patient-powered health and research advocate, applying herself in different areas of clinical research, digital health and patient engagement initiatives. Eva is especially interested in the development and promise of novel approaches to address breast cancer risk assessment, reduction, early detection, treatment, and survivorship.

Eva's interests and areas of expertise (e.g. multicultural marketing, precision medicine and patient-powered research and engagement) are instrumental to her research advocacy work. As a member of a research project team or patient community initiative, Eva can offer the following:

- Help ensure that potential participants have a basic awareness of the disease/issues that exist, and that the study synopsis and the benefit of a successful outcome are relevant and engaging
- Help ensure that the research protocol design makes sense from a participant perspective
- Help identify potential hurdles to participation and adherence and ways to overcome those hurdles wherever possible
- Help develop engaging recruitment, enrollment and adherence materials and communications plans to ensure broad participation and adherence
- Help set up and facilitate patient advisory panels for ongoing feedback from potential and actual trial participants
- Help ensure that stakeholders (patients, caregivers, family members, nurses, doctors, etc.) most impacted by findings of the research receive notifications of those findings, in formats that are developed to best engage each target audience

B. Positions and Honors

Employment

+ Over 25 years of experience developing consumer-centered marketing programs for a wide variety of packaged goods, financial services and non-profit organizations. Founder and president of a national advertising agency and marketing consultancy that focused on the rapidly-growing US Hispanic market, specializing in developing engaging and relevant programs targeting first-generation immigrants.

+ EDITH SANFORD BREAST CANCER FOUNDATION
  Sioux Falls, SD
  VP, Marketing and Leadership Team Member 2012-2014
  Recruited to help launch a national non-profit organization to support cutting-edge technology and translational genomic research to personalize breast cancer prevention and treatment, that was seeded with a $100M donor gift. Primarily responsible for developing engaging peer-to-peer programs and building alliances with strategically-aligned corporations and organizations. Additional responsibilities: multichannel CRM database set-up, direct marketing

Patient Research Advocacy

+ Patient Advocate, Cancer Protocol Committee, Duke Cancer Institute
+ Translational Research Executive Committee member, Alliance for Clinical Trials in Oncology
+ Patient Advocate, Community Oncology and Prevention Committee member, Alliance for Clinical Trials in Oncology

+ Patient Advocate Working Group member, Translational Breast Cancer Research Consortium
+ PCORI (Patient-Centered Outcomes Research Institute) – Patient Reviewer and inaugural member of Patient Reviewer Editorial Board
+ Consumer reviewer of research applications submitted to the Breast Cancer Research Program (BCRP) sponsored by the Department of Defense
+ FORCE (Facing Our Risk of Cancer Empowered) Patient Research Advocate
+ Susan G. Komen Advocate in Science (AIS), advocate reviewer for Career Catalyst Research
+ Active involvement as the implementation team co-lead and writer in a PCORI grant research study defining a roadmap for patient engagement in imaging Comparative Effectiveness Research

Additional Community Involvement
+ FORCE (Facing Our Risk of Cancer Empowered) Peer Navigator
+ Susan G. Komen - Co-Chair, AIS Membership Task Force
+ Acumen (the world's school for social change) – Community Catalyst for global online Social Enterprise courses and +Acumen Corps member
+ UNC – Chapel Hill – Komen Graduate Training in Disparities Research Mentor
+ Tech Entrepreneurship @StanfordE145_TE Global Online Course – Team Mentor
+ ABOUT Network (American BRCA Outcomes and Utilization of Testing Patient-Powered Research Network) - member
+ PCORnet (National Patient-Centered Clinical Research Network) – member
+ Love Army of Women – member

Recent Conference Attendance
ASCO Conference, Chicago – Conquer Cancer Foundation Scholarship - 2017
Precision Medicine World Conference - 2017
mHealth@Duke: The Lifecycle of Digital Health Science - 2017
PCORI Annual Meeting – PCORI Scholarship – 2017
AACR Conference – Scientist <--> Survivor Program – 2018
Alliance for Clinical Trials in Oncology Spring Group Meeting – 2018
Translational Breast Cancer Research Consortium Meeting – 2018
Advancing Anticancer Agent Development and Validation (AAADV) Workshop - 2018

Professional Affiliations
ASCO (American Society of Clinical Oncology)
NBCC (National Breast Cancer Coalition)
DH@HSL (Digital Health @ Health Sciences Library)
PCORI (Patient-Centered Outcomes Research Institute)

C. Contributions to Science

1) Eva seeks out meaningful opportunities to help ensure that clinical research is developed and implemented using **patient-centered design and communications**, resulting in more effective recruiting from a broader population base, better adherence, and greater impact.
   + FORCE (Facing Our Risk of Cancer Empowered) Patient Research Advocate
   + Susan G. Komen Advocate in Science (AIS)
   + Translational Research Executive Committee member, Alliance for Clinical Trials in Oncology
   + Patient Advocate Committee member, Alliance for Clinical Trials in Oncology
   + Patient Advocate Working Group member, Translational Breast Cancer Research Consortium
   + Active involvement as the implementation team co-lead and writer in a PCORI grant research study defining a roadmap for patient engagement in imaging Comparative Effectiveness Research

2) Eva seeks out meaningful opportunities to help ensure that clinical research is conducted to **ensure patient rights, safety and welfare** and that patient communications are understandable, transparent and honest.
   + Patient Advocate, Cancer Protocol Committee, Duke Cancer Institute

3) Eva seeks out participation on **research teams** where she can help ensure that all aspects of research are patient-centered and engaging, with active involvement in the development of the research question, project design, oversight, recruitment, and evaluation, as well as other significant aspects of the proposed project.
   + "Cancer Cell Intrinsic and Extrinsic Actions of Steroid Hormones in Breast Tumors", Breast Cancer Research Program (BCRP) Innovator Award from the United States Department of Defense Office of Congressionally Directed Medical Research Programs (CDMRP), PI: Donald McDonnell, PhD

3) Eva seeks out meaningful opportunities to participate on **grant review teams** to ensure that the patient's voice is heard when determining how funding should be allocated and selecting the most promising projects.
   + Consumer reviewer of research applications submitted to the Breast Cancer Research Program (BCRP) sponsored by the Department of Defense
   + PCORI (Patient-Centered Outcomes Research Institute) Peer Reviewer
   + Advocate reviewer, Susan G. Komen Career Catalyst Research – New Treatments for Drug Resistant Breast Cancers and Career Catalyst Research – Competitive Renewal Applications

4) Eva seeks out meaningful opportunities to participate in **peer reviews** to ensure that research studies and their findings are relevant and useful to the patient community.
   + PCORI (Patient-Centered Outcomes Research Institute) – Patient Reviewer and inaugural member of Patient Reviewer Editorial Board

D. Additional Information: Research Support and/or Scholastic Performance
N/A

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Wangensteen, Kirk

eRA COMMONS USER NAME (credential, e.g., agency login): wangensteen

POSITION TITLE: Assistant Professor of Medicine and Genetics

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	END DATE MM/YYYY	FIELD OF STUDY
Northwestern University, Evanston, IL	BA	06/2000	Biological Sciences
University of Minnesota, Minneapolis, MN	PHD	01/2007	Biochem, Mol Bio, and Biophysics
University of Minnesota, Minneapolis, MN	MD	05/2009	Medicine
University of Vermont, Burlington, VT	Resident	06/2011	Internal Medicine
University of Pennsylvania, Philadelphia, PA	Postdoc	06/2012	Liver Biology and Genetics
University of Pennsylvania, Philadelphia, PA	Fellow	06/2015	Gastroenterology

A. Personal Statement

My areas of expertise are in liver biology, liver cancer (namely hepatocellular carcinoma, HCC), gastroenterology, and genetics. I focus on unraveling the genetic pathways that enable hepatocyte repopulation in the setting of liver injury and – in the setting of prolonged injuries or deregulation of oncogenes – lead to cancer.

HCC is prevalent worldwide, has a high mortality rate, and has few effective treatment options. Previous efforts to discover targets in HCC have relied on *in vitro* or low-throughput *in vivo* methods. My lab aims to discover new treatments by applying highly innovative approaches to mice including performing powerful genetic screens *in vivo* in the hepatocytes of the liver. We have already succeeded to perform a drug susceptibility screen to discover synergism between the only FDA-approved therapeutic for HCC, sorafenib, and a novel drug compound that activates a nuclear receptor, LXR. We are expanding on this approach to uncover additional targets.

I am a physician-scientist with 80% of my time devoted to research and 20% to caring for patients with gastrointestinal diseases including liver cancer, which is predominantly hepatocellular carcinoma (HCC). This devastating cancer has a 5-year survival rate of less than 18% according to the SEER database. Cure is possible by liver transplantation, but this is available to only a minority of patients as HCC is usually too advanced at the time it is detected. Current drug treatments improve survival by a median of only 2-3 months; thus, new treatment options are desperately needed. In the clinic, I perform diagnostic tests, conduct counseling, evaluate laboratory test results, recommend treatments, and complete genetic testing for mutations that predispose patients to developing gastrointestinal cancers. I often observe the destructive consequences of liver cancer and the severe impact on patients and their families. Indeed, the major driving force for my lab and clinic is to one day bring about new therapies that may offer patients sustained remission from HCC.

Key publications:

1. Kieckhaefer JE, Maina F, Wells R, **Wangensteen KJ**: Liver cancer gene discovery using gene targeting, *Sleeping Beauty*, and CRISPR/Cas9. Seminars in Liver Disease 2019 Notes: In press.
2. **Wangensteen KJ**, Wang YJ, Dou Z, Wang AW, Mosleh-Shirazi E, Horlbeck MA, Gilbert LA, Weissman JS, Berger SL, Kaestner KH. Combinatorial genetics in liver repopulation and carcinogenesis with a in vivo CRISPR activation platform. Hepatology. 2018 Aug;68(2):663-676. PubMed PMID: 29091290; PubMed Central PMCID: PMC5930141.
3. Dou Z, Ghosh K, Vizioli MG, Zhu J, Sen P, **Wangensteen KJ**, Simithy J, Lan Y, Lin Y, Zhou Z, Capell BC, Xu C, Xu M, Kieckhaefer JE, Jiang T, Shoshkes-Carmel M, Tanim KMAA, Barber GN, Seykora JT, Millar SE, Kaestner KH, Garcia BA, Adams PD, Berger SL. Cytoplasmic chromatin triggers inflammation in senescence and cancer. Nature. 2017 Oct 19;550(7676):402-406. PubMed PMID: 28976970; PubMed Central PMCID: PMC5850938.

4. **Wangensteen KJ**, Zhang S, Greenbaum LE, Kaestner KH. A genetic screen reveals Foxa3 and TNFR1 as key regulators of liver repopulation. Genes Dev. 2015 May 1;29(9):904-9. PubMed PMID: 25934503; PubMed Central PMCID: PMC4421979.

B. Positions and Honors

Positions and Employment

2015 - 2017 Instructor in Medicine, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA

2018 - Assistant Professor of Medicine and Genetics, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA

Other Experience and Professional Memberships

2010 - Field Partner, Doctors Without Borders

2010 - Member, American Association for the Study of Liver Disease (Appointee to the Hepatobiliary Neoplasia Membership & Mentorship Subcommittee)

2012 - Member, American Gastroenterological Association

2016 - Member, American Association for the Advancement of Science

2017 - Member, International Liver Cancer Association

Honors

2000 Merit-based scholarship, Northwestern University

2000 Graduation with B.A. Summa Cum Laude, Northwestern University

2005 Finalist, Fulbright Fellowship to Spain

2007 Ruth L. Kirschstein National Research Service Award, National Institutes of Health

2007 Jacob Kaplan Award for Gastroenterology Research, Minnesota Medical Foundation

2007 Jan Lunden Award for Molecular Hepatology Research, Minnesota Medical Foundation

2009 Graduating Medical Student Research Award, Minnesota Medical Foundation

2014 Award Winner, 52nd Annual Komarov Research Competition, Philadelphia Gastroenterology Research Forum

2015 Frank Brooks Research Award for Gastroenterology Fellows, University of Pennsylvania

2017 Junior Investigator Award, International Liver Cancer Association

2017 Finalist, Career Awards for Medical Scientists, Burroughs-Wellcome Fund

2017 Holmes Award for Best Early Career Faculty Abstract, Department of Medicine, University of Pennsylvania

2018 Young Physician-Scientist Award, The American Society for Clinical Investigation

2018 Selected for an oral presentation, AASLD/EASL Masterclass

C. Contribution to Science

1. *Regenerative Biology and Cancer*: There is a shortage of liver organs for transplantation, and stem cell-derived hepatocytes may provide an alternative to liver organ transplantation. To better understand how the liver recovers from injury – and to identify targets for treatment of liver injury – I examined the gene expression pattern of repopulating hepatocytes to discover a crucial role for redox signaling in driving recovery from liver injury. I have investigated how hepatocytes can reverse senescence to undergo continuous proliferation after transplantation to the injured liver. I have also determined that hepatocytes, not hepatic progenitor cells, are the cell of origin of HCC, by performing genetic lineage tracing. Finally, I investigated stem cell signaling in the gut, and helped find a novel and critical cell type that surrounds the gut crypts, termed the telocyte.

    a. Wang AW*, **Wangensteen KJ***, Wang YJ, Zahm AM, Moss NG, Erez N, Kaestner KH. TRAP-seq identifies cystine/glutamate antiporter as a driver of recovery from liver injury. J Clin Invest. 2018 Jun 1;128(6):2297-2309. PubMed PMID: 29517978; PubMed Central PMCID: PMC5983312. *co-first authors.

    b. Shoshkes-Carmel M, Wang YJ, **Wangensteen KJ**, Tóth B, Kondo A, Massasa EE, Itzkovitz S, Kaestner KH. Subepithelial telocytes are an important source of Wnts that supports intestinal crypts. Nature. 2018 May;557(7704):242-246. PubMed PMID: 29720649; PubMed Central PMCID: PMC5966331.

c. Shin S*, **Wangensteen KJ***, Teta-Bissett M*, Wang YJ, Mosleh-Shirazi E, Buza EL, Greenbaum LE, Kaestner KH. Genetic lineage tracing analysis of the cell of origin of hepatotoxin-induced liver tumors in mice. Hepatology. 2016 Oct;64(4):1163-1177. PubMed PMID: 27099001; PubMed Central PMCID: PMC5033674. *co-first authors.
d. Wang MJ, Chen F, Li JX, Liu CC, Zhang HB, Xia Y, Yu B, You P, Xiang D, Lu L, Yao H, Borjigin U, Yang GS, **Wangensteen KJ**, He ZY, Wang X, Hu YP. Reversal of hepatocyte senescence after continuous in vivo cell proliferation. Hepatology. 2014 Jul;60(1):349-61. PubMed PMID: 24711261.

2. *Transposon biology*: Whole genome sequencing of organisms including zebrafish, mouse and humans has led to a wealth of information about gene sequences, and has revolutionized approaches to understand disease biology. I have been involved with a number of projects using DNA transposons to characterize gene function through screening, overexpression, and gene deletion techniques. I helped to develop the *Sleeping Beauty* and *Tol2* transposon systems for *in vivo* genetic screens in the zebrafish, and for gene transfer in human cell lines and in mice, including for germline gene transfer and for liver gene therapy.

a. Ni J, **Wangensteen KJ**, Nelsen D, Balciunas D, Skuster KJ, Urban MD, Ekker SC. Active recombinant Tol2 transposase for gene transfer and gene discovery applications. Mob DNA. 2016;7:6. PubMed PMID: 27042235; PubMed Central PMCID: PMC4818426.
b. Keng VW, Ryan BJ, **Wangensteen KJ**, Balciunas D, Schmedt C, Ekker SC, Largaespada DA. Efficient transposition of Tol2 in the mouse germline. Genetics. 2009 Dec;183(4):1565-73. PubMed PMID: 19805821; PubMed Central PMCID: PMC2787440.
c. Wilber A*, **Wangensteen KJ***, Chen Y, Zhuo L, Frandsen JL, Bell JB, Chen ZJ, Ekker SC, McIvor RS, Wang X. Messenger RNA as a source of transposase for sleeping beauty transposon-mediated correction of hereditary tyrosinemia type I. Mol Ther. 2007 Jul;15(7):1280-7. PubMed PMID: 17440442. *co-first authors.
d. Balciunas D, **Wangensteen KJ**, Wilber A, Bell J, Geurts A, Sivasubbu S, Wang X, Hackett PB, Largaespada DA, McIvor RS, Ekker SC. Harnessing a high cargo-capacity transposon for genetic applications in vertebrates. PLoS Genet. 2006 Nov 10;2(11):e169. PubMed PMID: 17096595; PubMed Central PMCID: PMC1635535.

3. *Clinical Gastroenterology*: I have focused on gastrointestinal diseases. I published a review on hepatitis C screening, treatment, and outcomes, including a discussion on the importance of screening for hepatocellular carcinoma. I also reported on unusual cases encountered in the clinic. One example was a case study and review of rare cases of massive hemorrhoidal bleeding after prostate biopsy. I published a case series of parkinsonism in patients treated for hepatitis C using interferon, includes a review of the literature on the possible association between interferons and Parkinson's disease. I also published a report of the first case of pre-surgical diagnosis of myointimal hyperplasia of the mesenteric veins, a rare disease of the gut vasculature. Diagnosis prior to surgical intervention led to a safe approach and a good outcome for the patient. I participated in a retrospective study investigating the clinical outcomes of patients with autoimmune hepatitis and coincident nonalcoholic steatohepatitis.

a. Mahmud N, **Wangensteen KJ**. Endoscopic Band Ligation to Treat a Massive Hemorrhoidal Hemorrhage Following a Transrectal Ultrasound-Guided Prostate Biopsy. Ann Coloproctol. 2018 Feb;34(1):47-51. PubMed PMID: 29535988; PubMed Central PMCID: PMC5847404.
b. De Luca-Johnson J, **Wangensteen KJ**, Hanson J, Krawitt E, Wilcox R. Natural History of Patients Presenting with Autoimmune Hepatitis and Coincident Nonalcoholic Fatty Liver Disease. Dig Dis Sci. 2016 Sep;61(9):2710-20. PubMed PMID: 27262844.
c. **Wangensteen KJ**, Krawitt EL, Hamill RW, Boyd JT. Parkinsonism in Patients With Chronic Hepatitis C Treated With Interferons: Case Reports and Review of the Literature. Clin Neuropharmacol. 2016 Jan-Feb;39(1):1-5. PubMed PMID: 26757310.
d. **Wangensteen KJ**, Fogt F, Kann BR, Osterman MT. Idiopathic Myointimal Hyperplasia of the Mesenteric Veins Diagnosed Preoperatively. J Clin Gastroenterol. 2015 Jul;49(6):491-4. PubMed PMID: 25626629.

Complete List of Published Work in My Bibliography:
https://www.ncbi.nlm.nih.gov/myncbi/kirk.wangensteen.1/bibliography/40417448/public/

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

K08 DK106478-01 Wangensteen (PI) 07/15/15-04/30/20
NIH/NIDDK
Genetic basis of liver repopulation
The hypothesis we test in this proposal is that Foxa3 and TNFR1 play critical roles in regulating liver regeneration. We propose the following Aims: (1) To investigate the mechanisms underlying Foxa3-mediated promotion of liver repopulation. (2) To assess whether TNFR1 deletion and targeted anti-TNF therapy can promote liver repopulation.
Role: PI

McCabe Fund Award Wangensteen (PI) 07/01/18-06/30/19
The Thomas B. McCabe and Jeannette E. Laws McCabe Fund
Elucidating mechanisms and treatments for liver cancer through a novel in vivo CRISPR screening platform
The overarching goal of this proposal is to discover new targets and treatments in HCC using an innovative in vivo genetic screening platform. Aim 1 is to identify target genes that are sufficient and necessary for HCC and Aim 2 is to develop novel drugs for HCC in vivo.
Role: PI

TAPITMAT Wangensteen (PI) 02/01/19-01/31/21
The Institute for Translational Medicine and Therapeutics (ITMAT)
Strategy to safely repopulate the uninjured host liver with engineered hepatocytes
To identify factors capable of driving liver repopulation in uninjured liver by performing an unbiased *in vivo* CRISPRa screen for novel genes or combinations of genes that promote tumor-free hepatocyte engraftment and proliferation.
Role: MPI

Sub of P30-DK050306 Wangensteen (PI) 07/01/15-06/30/16
NIH/NIDDK
Germline genetics of liver cancer
To determine the prevalence of germline mutations in patients with current or previous diagnosis of HCC, and to uncover whether subgroups are at higher risk, such as patients with a family history of cancers.
Role: PI

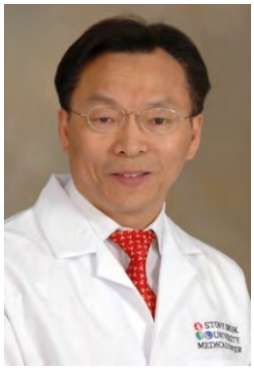
5T32DK007066 Wang (PI) 09/01/17-08/31/20
NIH/NIDDK
Elucidating Redox Regulation In The Repopulating Liver
This study will address The question of whether replicating hepatocytes have higher or lower redox states relative to quiescent hepatocytes. In addition, I will perturb The level of expression of Slc7a11 and to assess The effect on The liver's Redox state. This study will provide an in-depth understanding of temporal and regional specificity of redox regulation during Liver repopulation and will identify novel potential targets that might be employed for the treatment of acute Liver *Injury* by inducing *Hepatocyte* replication.
Role: Co-mentor

Completed Research Support

Pilot Grant Wangensteen (PI) 07/01/16-06/30/17
American Gastroenterological Association
Massively parallel CRISPRa screen to discover drivers of liver repopulation
We hypothesize our screen will uncover the most important genetic pathways driving liver repopulation, and will allow us to identify novel drug targets. Furthermore, our first-ever in vivo CRISPRa system will be a valuable resource for the biomedical community including the AGA.
Role: PI

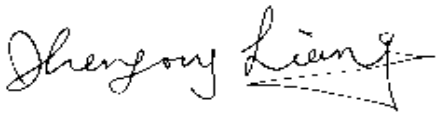
Sub of P30-DK050306 Wangensteen (PI) 07/01/15-06/30/16
NIH/NIDDK
Elucidation of the genetic profile of repopulating hepatocytes

Prior research on hepatocyte proliferation has focused on the easily accessible paradigm of partial hepatectomy, which does not model the regenerative response of hepatocytes following toxic injury, such as occurs following alcohol or acetaminophen poisoning or acute viral hepatitis. To address this knowledge gap, we propose to utilize an innovative model system to identify the genes that control hepatocyte proliferation in the context of toxic liver damage.
Role: PI



Jerome Zhengrong Liang gained a Ph.D. degree in Physics from City University of New York in 1987, followed by a one year Research Fellowship in Nuclear Medicine and Radiation Oncology at Albert Einstein College of Medicine. He then became a Research Associate and Assistant Professor in Radiology at Duke University Medical Center. He joined State University of New York at Stony Brook (SUNY-SB) in 1992 and currently holds a Professorship in the Departments of Radiology, Computer Science, Biomedical Engineering, and Electrical & Computer Engineering. He was a co-founder of the Program in Biomedical Engineering at SUNY-SB. His primary research interests in medical imaging include data acquisition geometry, image formation and processing methodology, and feature-based visualization and computer-aided detection and diagnosis. He has authored more than 400 scientific publications, 20 US patents, 45 invited talks, and 170 conference presentations. He has supervised more than 25 postdoctoral researchers and more than 40 graduate students (PhD and MS degrees). He has been principal investigator (PI) for 11 NIH projects and Co-PI for 4 NIH projects. He received the State University of New York Chancellor's Entrepreneur Award for "*one whose invention has led to the startup of a company to commercialize the product*" in 2002. He was elected Fellow to the IEEE for "*contributions to medical image reconstruction and virtual colonoscopy*" in 2007.

Yours truly,



Jerome Z. Liang, PhD, IEEE Fellow
Professor of Radiology, Computer Science, BME, and ECE
Director, IRIS Lab
APT Committee, School of Medicine
State University of New York at Stony Brook

CURRICULUM VITAE

Jerome Zhengrong Liang, Ph.D.

Professor of Radiology, Computer Science and Biomedical Engineering

State University of New York at Stony Brook, School of Medicine/Health Sciences Center
Department of Radiology, 4th Floor, Room 120, Stony Brook, NY 11794-8460

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Working Fax	(631) 444-6260(Off), -6450(Lab), -7538(Dept)
Visa Type and Number if not a Citizen:	United States of America
Email Address:	jzl@mil.sunysb.edu
URL Address:	http://www.mil.sunysb.edu/iris/jzl/jzl.html

HIGHER EDUCATION

(Including Internship, Residency & Other Formal Professional Training)

From	*To*	*Degree & Date*	*Institution & Location*	*Field*
03/1978	07/1981	B.S. (07/1982)	Lanzhou University of China	Physics
09/1981	11/1986	Ph.D. (02/1987)	City University of New York (CUNY)	Physics

Internships: N/A
Residencies: N/A

CERTIFICATION AND LICENSURE

(ECFMG, FLEX, National & Professional Boards & Licensure)

Date	Agency
N/A	N/A

APPOINTMENTS

(Academic Appointments)

11/1985-10/1986	Research Fellowship at the Medical Physics Department of Memorial Sloan-Kettering Cancer Center (MSKCC), New York, NY 10021
11/1986-10/1987	Instructor Fellow in the Departments of Nuclear Medicine and Radiation Oncology, Albert Einstein College of Medicine (AECM), Bronx, NY 10467
11/1987-10/1989	Research Associate in the Department of Radiology, Duke University Medical Center (DUMC), Durham, NC 27710
11/1989-06/1992	Assistant Medical Research Professor in the Department of Radiology, DUMC, Durham, NC 27710
07/1992-02/1997	Assistant Professor in the Department of Radiology, State University of New York at Stony Brook (SUNY-SB), Stony Brook, NY 11794
07/1995-02/1997	Assistant Professor in the Department of Computer Science, SUNY-SB, Stony Brook, NY 11794
03/1997-05/2000	Associate Professor (tenured) in the Department of Radiology, SUNY-SB, Stony Brook, NY 11794
03/1997-05/2000	Associate Professor in the Department of Computer Science, SUNY-SB, Stony Brook, NY 11794
09/1997-08/2000	Part-time Associate Professor of Peking University, Beijing, China 100871
07/1995-present	Co-Director of the Program in Biomedical Engineering (BME), SUNY-SB, Stony Brook, NY 11794

09/1997-present	Adjunct Scientist Staff in the Medical Department of Brookhaven National Laboratory (BNL), Upton, NY 11973
09/2000-present	Part-time Professor of Peking University, Beijing, China 100871
09/2000-present	Part-time Professor of the General (301) Medical University of China, Beijing, China 100801
05/2001-present	Part-time Professor of the Fourth General Medical University of China, Xi'An, China 710032
06/2000-present	Professor (tenured) in the Department of Radiology, SUNY-SB, Stony Brook, NY 11794
06/2000-present	Professor in the Department of Computer Science, SUNY-SB, Stony Brook, NY 11794

OTHER APPOINTMENTS

(Hospital or Agency Staff)

From	*To*	*Title*	*Status*	*Institution & Location*
11/1986	10/1987	Medical Physicist	Physicist	Montefiore Med Center of AECM
07/1992	06/1995	Medical Physicist	Physicist	University Hospital at Stony Brook
05/1998	present	Technical Advisor	Advisory Board	MD OnLine, Inc, Boston, MA
01/1999	present	VP for R & D	Founder/Board	Viatronix, Inc, Stony Brook, NY

By the appointment of Medical Physicist at SUNY-SB, I had made a significant contribution to establish computer network among the clinical sites of Radiology Department, as well as the network communication between the clinical sites and the Medical Imaging Laboratories of the Department. I also contributed significantly to upgrade the equipment and purchase new imaging scanners in the Nuclear Medicine Division of Radiology Department at SUNY-SB.

I am the Principal Investigator of virtual colonoscopy project at Stony Brook and a Founder of Viatronix, Inc, which develops virtual colonoscopy and other Medical Imaging software as commercial products. I have played an important role for the creation of MD OnLine, Inc.

PROFESSIONAL PRACTICE AND SERVICES

Activity	*Location*	*Institution & Location*
External Funding Review Committee		
Committee Member	Maryland	NIH Study Section (Initial Review Group for Diagnostic Imaging, 1998-present)
Committee Member	Hong Kong	Research Grants Council (Review for Medical Imaging Grants, 2000-present)
Journal Editorial Service		
Associate Editor	New Jersey	Journal of IEEE Transactions on Medical Imaging (1999 – present)
Guest Editor	Beijing, China	Chinese Journal of Medical Physics (1999 – present)
Editor	New Jersey	Special Issue of IEEE Trans. Med Imaging on Virtual Endosocpy (2003).
National/International Conference Organization/Review Committee		
Committee Member	New Jersey	Annual Meeting of IEEE Nuclear Sciences & Medical Imaging (1996 – present)
Committee Member	Virginia	Annual Meeting of the Society of Nuclear Medicine (1996 – present)
Committee Member	Beijing, China	International Workshop on Medical Imaging Physics and Engineering, 1996
Committee Member	Boston	Prospect, Opportunity, and Challenge in 21st Century Biomedical Science Cooperation Among Chinese Sciences in China and USA, 1999
Committee Member	Virginia	Multiple Sclerosis Practical Guidelines Summit: *Advances in the Evaluation of MS patients*, 2001
Committee Member	Beijing, China	International Workshop on Medical Imaging Physics and Engineering, 2001
Committee Member	Beijing, China	CUSPEA Convention on Physics in 21st Century, 2002
Panelist of CAD	Paris, France	16th Intl Congress and Exhibition of Computer Assisted Radiology, 2002
Journal Reviewer		
Reviewer	New York	Journal of Medical Physics (1987 – present)
Reviewer	London	Journal of Physics in Medicine and Biology (1987 – present)
Reviewer	New Jersey	Journal of IEEE Transactions on Nuclear Science (1987 – present)
Reviewer	New Jersey	Journal of IEEE Transactions on Medical Imaging (1987 – present)
Reviewer	Virginia	Journal of Nuclear Medicine (1989 – present)

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Reviewer	New York	International Journal of Imaging Systems and Technology (1989 – present)
Reviewer	New York	Journal of Electronic Imaging (1992 – present)
Reviewer	New Jersey	Journal of IEEE Transactions on Image Processing (1994 – present)

Other Professional Services

Collaborator	New York	Multiple Energy CT by the National Synchrotron Source of Brookhaven National Laboratory (BNL) (1996 – present)
Collaborator	New York	Quantitative PET and SPECT Functional Imaging of Radiotracers in the Medical Department of BNL (1997 – present)
Board of Trustees	New York	Association of American-Chinese Professionals, Inc. (1994 – present)
Judge committee	New York	Lea Ronal High School Science Affair (1998 – present)

PROFESSIONAL AND SCIENTIFIC SOCIETIES

Organization	*Date of Initial Membership*
Intl Society for Magnetic Resonance in Medicine (SMRM)	01/97
American Association of Physicists in Medicine (AAPM)	02/87
Institute of Electrical & Electronics Engineers (IEEE)	02/87
The Society of Nuclear Medicine (SNM)	11/87
Society of Photon-Optical Instrument Engineers (SPIE)	02/87
American Physics Society (APS)	09/82

ACADEMIC AND PROFESSIONAL HONORS

Organization	*Honor*
China-US Physics Examination Award	Top 20 among more than 100,000 candidates (1981)
CUNY	Fellowship Award (1981-1983)
AECM	Fellowship Award (1986-1997)
National Institutes of Health (NIH)	First Investigator Award (1990-1995)
New York State	Term-Faculty Award (1994)
American Heart Association (AHA)	Established Investigator Award (1996-2001)
Radiological Society of North America (RSNA)	Certificate of Merit Award (1996)
Who's Who in America	In Science and Engineering (1996-1997)
New York State	Certificate of Appreciation (1999)
State University of New York	Chancellor's Entrepreneur Award (2002), *whose invention has led to the start up of a company to commercialize the product*

RESEARCH SUPPORT: GRANTS AND CONTRACTS

From	*To*	*Project*	*Amount*
		(***Previous Funding***)	
01/01/90	12/31/95	"Bayesian Reconstruction for Computed Tomography" funded by NIH (R29) PI: Jerome Z. Liang Co-PI: none	$506,862
02/15/94	02/14/95	"Efficient Imaging Algorithms" funded by Society of Thoracic Radiology (STR) PI: Jerome Z. Liang Co-PI: Jinghan Ye	$4,500
03/01/95	02/28/97	"Myocardial Perfusion Imaging by 180 degree Scan" funded by ADAC Company PI: Jerome Z. Liang Co-PI: Jinghan Ye	$24,940
07/01/96	06/30/98	"Development of Virtual Colonoscopy" funded by BioCenter-SB & E-Z-EM Inc. PI: Jerome Z. Liang Co-PIs: Arie E. Kaufman and Mark R. Wax	$75,000
06/01/96	05/31/99	"Establishing a Program in Biomedical Engineering at SUNY at Stony Brook" funded by the Whitaker Foundation; Jerome Z. Liang serves as a Co-PI	$996,906
08/01/98	07/31/00	"Colon Segmentation for Virtual Colonoscopy" funded by NIH (R21) PI: Jerome Z. Liang Co-PI: Arie E. Kaufman	$281,208
09/01/96	08/31/00	"Analytical Approaches to Quantitative Brain SPECT" funded by NIH (R01) PI: Jerome Z. Liang Co-PI: none	$672,252
07/01/96	06/30/01	"Clinical Assessment in Myocardial Perfusion Imaging" EI Award of AHA PI: Jerome Z. Liang Co-PI: none	$298,750
09/01/99	08/31/01	"Imaging Informatics in Cyberspace" funded by Mediol.Com Corporation	$342,495

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		PI: Jerome Z. Liang Co-PI: none	
07/01/00	06/30/01	"3D Analysis of Aortic Aneurysm & Stent Grafts" by BioCenter-SB/ViatronixInc	$80,000
		PI: Arie E. Kaufman Co-PI: Jerome Z. Liang	
07/01/01	06/30/02	"New York State Technology and Academic Research" funded by NYSTAR	$500,000
		PI: John Roberts Co-PI: Arie E. Kaufman and Jerome Z. Liang	
09/01/01	08/31/02	"Interdisciplinary Program in Biomedical Research" funded by NIH (R25)	$100,000
		PI: Clinton Rubin Co-PI: Jerome Z. Liang, *et al*.	
		(***On Going Projects***)	
02/01/96	07/31/02	"Quantitative SPECT Reconstruction of the Chest" funded by NIH (R01)	$1,570,446
		PI: Jerome Z. Liang Co-PI: none	
03/01/01	02/28/04	"Developing Virtual Colonoscopy for Cancer Screening" funded by NIH (R01)	$1,424,966
		PI: Jerome Z. Liang Co-PI: Arie E. Kaufman	
		(***Pending Proposals***)	
12/01/03	11/31/06	"Quantitative Analysis for MS Using MRI and MRS" pending by NIH	$1,259,827
		PI: Jerome Z. Liang Co-PI: Lauren B. Krupp	
12/01/03	11/31/06	"Noise Reduction Toward Low-Dose Computed Tomography" pending by NIH	$831,000
		PI: Jerome Z. Liang Co-PI: Hongbing Lu	
12/01/03	11/31/05	"MRI Virtual Cystoscopy: Early Bladder Cancer Detection" pending by NIH	$295,000
		PI: Jerome Z. Liang Co-PI: Wei Huang	
12/01/03	11/31/05	"Computer-Aided Surgical Planning for Otologic Surgery" pending by NIH	$556,800
		PI: Eric E. Smouha Co-PI: Jerome Z. Liang	

By the above grants, I have built up a well-equipped research Laboratory for Imaging Research and Informatics (IRIS). The detailed research description can be found in the lab homepage: **http://www.mipl.rad.sunysb.edu/micl**. I have contributed significantly to establish the collaborative research among Departments of Radiology, Computer Science, Neurology, Surgery, and Applied Mathematics, as well as the research between the Radiology Department and the Medical Physics Department of BNL. I am the first to bring the idea to Radiology Department of establishing BME by applying for the Whitaker Biomedical Engineering Education fund. My contribution to the BME Program at Stony Brook is significant.

COURSES DIRECTED

Date	*Institution*	*Title*	*Enrollment*
01/1976-09/1980	Comm. College	Math, Physics, Chemistry, History, and Lab	>50
09/1981-11/1986	CUNY (Physics)	Lab instruction, Lecture Assistance	>90
07/1993-present	SUNY-SB (Electrical Engineering)	Instrumentation of Modern Medical Imaging	>10
09/1995-present	SUNY-SB BME Program	Engineering Principles in Diagnostic Imaging	>15

STUDENTS SUPERVISED

Candidate	*Title*	*Institution*	*Date*
Jui-Hsi Cheng	Quantitative Brain SPECT	Electrical Engineering Dept of SUNY-SB	06/97 (PhD)
Feng Yang	Segmentation for CT Colonoscopy	Computer Science Dept of SUNY-SB	06/98 (M.S.)
Jianzhong Jiang	Functional Medical Imaging	Physics Dept of SUNY-SB	06/98 (M.S.)
Xuejun Hao	Quantitative Image Edge Analysis	Computer Science Dept of SUNY-SB	06/99 (M.S.)
Qianjiang Mao	Myocardial Perfusion SPECT	Electrical Engineering Dept of SUNY-SB	06/00 (M.S.)
Qing Chu	Quantitative MRI Analysis	Electrical Engineering Dept of SUNY-SB	06/00 (M.S.)
Yi Li	Algorithm Interface Program	Computer Science Dept of SUNY-SB	06/00 (M.S.)
Daeki Yoon	Quantitative Image Analysis	Applied Math Dept of SUNY-SB	12/00 (M.S.)
Daniel Hseuh	Quantitative Image Analysis	Biomedical Engineering Dept of SUNY-SB	12/00 (M.S.)
Guoping Han	Quantitative Chest SPECT	Physics Dept of SUNY-SB	08/01 (PhD)
Lihong Li	Segmentation of MRI for Stroke	Electrical Engineering Dept of SUNY-SB	12/02 (PhD)
Tianfang Li	Cerebral Perfusion SPECT	Physics Dept of SUNY-SB	06/03 (PhD)
Daria Eremina	Quantitative MRI for MS	Applied Math Dept of SUNY-SB	06/05 (PhD)
Jing Wang	Low-Dose CT	Physics Dept of SUNY-SB	06/05 (PhD)
R. Ayanzen	(research training in imaging)	NY Medical College	07/92-02/93

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L. Jiang	(research training in imaging)	Heart Rehabilitate Lab	07/94-02/95

POSTDOCTORS SUPERVISED

Name	*From*	*To*	*Institution*	*Title*
Jinghan Ye, Ph.D.	01/1993	01/1996	Radiology Dept of SUNY-SB	Myocardial Perfusion SPECT
Jian Li, Ph.D.	09/1996	08/1999	Radiology Dept of SUNY-SB	Quantitative Chest SPECT
Jiangsheng You, Ph.D.	03/1997	09/2000	Radiology Dept of SUNY-SB	Quantitative Brain SPECT
Weidong Wang, Ph.D.	07/1997	08/1997	Radiology Dept of SUNY-SB	Segmentation of MR Images
Rui Chiou, Ph.D.	04/1998	03/2000	Depts of Radiol & Comp Sci, SUNY-SB	Virtual Colonoscopy (VC)
Dongqing Chen, Ph.D.	05/1998	08/2001	Radiology Dept of SUNY-SB	Segmentation for VC
Bin Li, Ph.D.	06/1998	08/2001	Radiology Dept of SUNY-SB	Graphics on Virtual Endoscopy
Michael Wan, Ph.D.	10/1998	09/2000	Depts of Radiol & Comp Sci, SUNY-SB	Volume Rendering
Hongbing Lu, Ph.D.	11/1999	10/2002	Radiology Dept of SUNY-SB	Gated Cardiac SPECT
Xiang Li, Ph.D.	09/2000	08/2003	Radiology Dept of SUNY-SB	Image Reconstruction
Zigang Wang, Ph.D.	09/2000	08/2003	Radiology Dept of SUNY-SB	Virtual Surgery System
Junhai Wen, Ph.D.	02/2001	01/2003	Radiology Dept of SUNY-SB	Image Reconstruction
Changkil Lee, Ph.D.	09/2001	01/2002	Radiology Dept of SUNY-SB	MS Evaluation

MEMBERSHIP IN DEGREE THESIS COMMITTEE

Candidate	*Institution*	*Degree & Thesis Project*
Chun-Ho Chang	EE Dept of SUNY-SB	Ph.D., "Segmenting MRI Using Atlas-Guided Deformable Contour Model"
Jong-Kae Fwu	EE Dept of SUNY-SB	Ph.D., "MRF Model Based Automatic Segmentation of Victor Images"
Lichan Hong	CS Dept of SUNY-SB	Ph.D., "Computer Graphics and Analysis in Medical Virtual Reality"
Xinzhou Wei	CS Dept of CUNY-NY	Ph.D., "The EI Gamal Digital Signature Scheme"

UNIVERSITY SERVICES

Date	*Activity*
1994-present	Faculty Advisor and Mentor Programs at SUNY-SB
1995-present	Committee Member, Asian American Forum at SUNY-SB
1999-present	Medical School Faculty Senate Committee at SUNY-SB

I am a founder of the Asian American Forum. The Forum contributes significantly to the Asian American Studies at SUNY-SB. It is this Forum that initialized the funding from the Computer Associates International (a Long Island computer software company) to establish an Asian American Center at Stony Brook.

PUBLICATIONS

Invited Refereed Articles:

[1] Z. Liang, R. Jaszczak, C. Floyd, K. Greer, and E. Coleman (1989), "Bayesian Reconstruction for SPECT: validation with Monte Carlo simulation, experimental phantom and real data," Intl J Imaging Systems & Technology, vol.1, no.1, 149-168.

[2] Z. Liang (1993), "Tissue Classification and Segmentation of MR Images," IEEE Engin Med Biology, vol.12, no.1, 81-85.

[3] Z. Liang and J. Ye (1993), "Quantitative SPECT Using Cone-Beam Collimation and Iterative FBP Reconstruction," Proc World Chinese Nuclear Medicine Society, vol.1, 128-132.

[4] Z. Liang, J. Ye, J. Cheng, and D. Harrington (1996), "Quantitative Brain SPECT in Three Dimensions: an analytical approach to non-uniform attenuation without transmission scans," in *Computational Imaging and Vision* book series, by Kluwer Academic Publishers, pp.117-132.

[5] Z. Liang, D. Wang, J. Ye, H. Li, C. Roque, and D. Harrington (1997), "Automating Brain Tissue Segmentation from Multispectral MR Images," 1st Intl Workshop on Physics and Engineering in Medical Imaging, Beijing, vol.69, 63-86.

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[6] Z. Liang (1997), "SPECT Instrumentation and Image Formation Methodology," 1st Intl Workshop on Physics and Engineering in Medical Imaging, Beijing, vol.69, 117-133.

[7] Z. Liang, S. Bao, J. You, W. Wang, and G. Han (2000), "Progress on the Development of High Spatial Resolution Imaging Techniques in Nuclear Medicine," Chinese J of Medical Physics, vol.17, no.2, 75-81.

[8] Z. Liang (2001), "Virtual Colonoscopy: an alternative approach to examination of the entire colon," INNERVISION, vol.16, no.10, 40-44.

[9] Z. Liang (2001), "A System and Method for Volumetric Analysis of Multiple Sclerosis Using Multispectral MRI," 2nd Intl Workshop on Physics and Engineering in Medical Imaging, Beijing, vol.135, 88.

[10] Z. Liang (2001), "Medical Imaging Informatics: from image formation and processing to visualization," 2nd Intl Workshop on Physics and Engineering in Medical Imaging, Beijing, vol.135, 89.

Refereed Journal Papers:

[1] Z. Liang and H. Hart (1987), "Bayesian Image Processing of Data from Constrained Source Distributions I: non-valued, uncorrelated and correlated constraints," Bulletin of Mathematical Biology, vol.49, no.1, 51-74.

[2] H. Hart and Z. Liang (1987), "Bayesian Image Processing of Data from Constrained Source Distributions II: valued, uncorrelated and correlated constraints," Bulletin of Mathematical Biology, vol.49, no.1, 75-91.

[3] Z. Liang and H. Hart (1987), "Bayesian Image Processing of Data from Constrained Source Distributions III: fuzzy pattern constraints," Physics in Medicine and Biology, vol.32, no.11, 1481-1494.

[4] H. Hart and Z. Liang (1987), "Bayesian Image Processing in Two Dimensions," IEEE TMI, vol.6, no.3, 201-208.

[5] H. Hart, A. Schoenfeld, and Z. Liang (1987), "Four Planar Detector Positron Emission Tomography," SPIE, Applications of Digital Image Processing X, vol.829, 201-204.

[6] Z. Liang and H. Hart (1988), "Source Continuity and Boundary Discontinuity Considerations in Bayesian Image Processing," Medical Physics, vol.15, no.5, 754-756.

[7] Z. Liang and H. Hart (1988), "Bayesian Reconstruction in Emission Computerized Tomography," IEEE Trans Nuclear Sciences, vol.35, no.1, 788-792.

[8] Z. Liang (1988), "Statistical Models of *A Priori* Information for Image Processing: neighboring correlation constraints," J Optical Society of America, vol.5, no.12, 2026-2031.

[9] Z. Liang, R. Jaszczak, and H. Hart (1988), "Study and Performance Evaluation of Statistical Methods in Image Processing," Computers in Biology and Medicine, vol.18, no.6, 395-408.

[10] Z. Liang (1988), "Image Enhancement by Estimated *A Priori* Information," SPIE, Medical Imaging II, vol.914, 684-689.

[11] Z. Liang (1988), "Statistical Models of *A Priori* Information for Image Processing, I," SPIE, Medical Imaging II, vol.914, 677-683.

[12] Z. Liang and R. Jaszczak (1988), "Statistical Models of *A Priori* Information for Image Processing, II: finite distribution range constraints," SPIE, Application of Digital Image Processing XI, vol.974, 53-58.

[13] Z. Liang (1988), "Preliminary Study of Triple Photon Coincidence Imaging Technique," SPIE, Applications of Digital Image Processing XI, vol.974, 283-291.

[14] Z. Liang, R. Jaszczak, and K. Greer (1989), "On Bayesian Image Reconstruction from Projections: uniform and non-uniform *a priori* source information," IEEE Trans Medical Imaging, vol.8, no.3, 227-235.

[15] Z. Liang, R. Jaszczak, C. Floyd, and K. Greer (1989), "A Spatial Interaction Model for Statistical Image Processing," Information Processing in Medical Imaging, vol.11, 29-43.

[16] Z. Liang and R. Jaszczak (1990), "Comparisons of Multiple Photon Coincidence Imaging Techniques," IEEE Trans Nuclear Sciences, vol.37, no.3, 1282-1292.

[17] Z. Liang and R. Jaszczak (1990), "The Discussion on *A Smoothed EM Approach to Indirect Estimation Problem, with Particular Reference to Stereology and Emission Tomography*," J R Statist Soc, vol.52, no.2, 317.

[18] Z. Liang (1990), "On Maximum Entropy Image Reconstruction from Projections via Lagrange Parameter Analysis," SPIE, Digital Image Synthesis and Inverse Optics, vol.1351, 56-68.

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[19] Z. Liang, R. Jaszczak, E. Coleman, and V. Johnson (1991), "Simultaneous Reconstruction, Segmentation, and Edge Enhancement of Relatively Piecewise Continuous Images with Intensity-Level Information," Medical Physics, vol.18, no.3, 394-401.

[20] Z. Liang, R. Jaszczak, and E. Coleman (1991), "On Reconstruction and Segmentation of Piecewise Continuous Images," Information Processing in Medical Imaging, vol.12, 94-104.

[21] Z. Liang (1991), "Implementation of Linear Filters for Iterative Penalized Maximum Likelihood SPECT Reconstruction," IEEE Trans Nuclear Sciences, vol.38, no.2, 606-611.

[22] Z. Liang, T. Turkington, D. Gilland, R. Jaszczak, and E. Coleman (1992), "Simultaneous Compensation for Attenuation, Scatter, and Detector Response for SPECT Reconstruction in Three Dimensions," Phys Med Biol, vol.36, no.3, 587-603.

[23] Z. Liang, R. Jaszczak, and E. Coleman (1992), "Parameter Estimation of Finite Mixtures Using the EM Algorithm and Information Criteria with Application to Medical Image Processing," IEEE Trans Nucl Science, vol.39, no.4, 1126-1133.

[24] Z. Liang (1993), "Compensation of Attenuation, Scatter, and Detector Response with an Iterative FBP Method for SPECT Reconstruction," Medical Physics, vol.20, no.4, 1097-1106.

[25] Z. Liang and J. MacFall (1993), "Automatic Tissue Segmentation from Computed Intrinsic MR Images," Soc Magn Reson Medicine, vol.2, 695.

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[27] Z. Liang (1994), "Detector Response Restoration in Image Reconstruction of High Resolution Positron Emission Tomography," IEEE Trans Medical Imaging, vol.13, no.2, 314-321.

[28] Z. Liang, J. MacFall, and D. Harrington (1994), "Parameter Estimation and Tissue Segmentation from Multispectral MR Images," IEEE Trans Medical Imaging, vol.13, no.3, 441-449.

[29] Z. Liang, J. Ye, and D. Harrington (1994), "An Analytical Approach to Quantitative Reconstruction of Non-Uniform Attenuated Brain SPECT," Physics in Medicine and Biology, vol.39, no.11, 2023-2041.

[30] J. Ye, Z. Liang, and D. Harrington (1994), "Quantitative Reconstruction for Myocardial Perfusion SPECT: an efficient approach by depth-dependent deconvolution and matrix rotation," Physics in Medicine Biology, vol.39, no.7, 1281-1293.

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[33] Z. Liang, J. Ye, J. Cheng, and D. Harrington (1996), "The Inversion of Exponential Radon Transform for Quantitative Brain SPECT," Physics in Medicine and Biology, vol.41, no.6, 1227-1232.

[34] M. Wagshul, T. Button, H. Li, Z. Liang, K. Zhong, and A. Wishnia (1996), *"In Vivo* MR Imaging and Spectroscopy Using Hyperpolarized Xe-129," Magn Reson Medicine, vol.36, no.1, 183-191.

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[37] Z. Liang, D. Wang, J. Ye, H. Li, C. Roque, and D. Harrington (1997), "Correction of RF Inhomogeneity for Automatic Segmentation from Multispectral MR Images," Soc Magn Reson Medicine, vol.3, 2042.

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[40] F. Dilmanian, X. Wu, …, Z. Liang, et al (1997), "Single- and Dual-Energy CT with Monochromatic Synchrotron X-Rays, "Physics in Medicine and Biology, vol.42: 371-387.

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[47] J. You, Z. Liang, and G. Zeng (1999), "A Unified Reconstruction Framework for Both Parallel-Beam and Variable Focal-Length Fan-Beam Collimators by a Cormack-Type Inversion of Exponential Radon Transform," IEEE Trans Medical Imaging, vol.18, no.1, 59-65.

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[49] R. Chiou, A. Kaufman, Z. Liang, L. Hong, and M. Achniotou (1999), "Interactive Fly-Path Planning Using Potential Fields and Cell Decomposition for Virtual Endoscopy," IEEE Trans Nuclear Sciences, vol.46, no.4, 1045-1049.

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[51] R. Chiou, D. Chen, Z. Liang, and A. Kaufman (1999), "Volume Segmentation and Rendering of Mixtures of Materials for Virtual Colonoscopy," SPIE Medical Imaging, vol.3660, 133-138.

[52] J. Li, Z. Liang, J. Ye, and G. Han (1999), "Implementation and Preliminary Investigation of Analytical Methods for Correction of Distance-Dependent Resolution Variation and Uniform Attenuation in 3D Brain SPECT," IEEE Trans Nuclear Science, vol.46, no.6, 2162-2171.

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[56] D. Chen, B. Li, W. Huang, and Z. Liang (2000), "A Multi-Scan MRI-Based Virtual Cystoscopy," SPIE Medical Imaging, vol.3978, 146-152.

[57] B. Li, D. Chen, E. Smouha, and Z. Liang (2000), "Computer Aided Surgical Planning for Congenital Aural Atresia," SPIE Medical Imaging, vol.3976, 394-400.

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UNITED STATES PATENTS:

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[2] A. Kaufman, Z. Liang, M. Wax, A. Viswambharan, and L. Hong (1996), *System and Method for Performing a Three-Dimensional Virtual Examination*, Serial Number 08/714,697, Patent Number 5,971,767.

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[4] A. Kaufman, Z. Liang, M. Wax, D. Chen, and M. Wan (1999), *System and Method for Performing a Three-Dimensional Virtual Segmentation and Examination with Optical Texture Mapping*, Serial Number 09/343,012 S1.

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[11] A. Kaufman, Z. Liang, M. Wax, M. Man, I. Bitter, D. Chen, F. Dachille, K. Kreeger, and S. Lakare (2001), *Enhanced Navigation and Detection for Virtual Examination*, Serial Number 60/237,311 S1.

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[14] A. Kaufman, F. Dachille, M. Wan, M. Wax, K. Kreeger, and Z. Liang (2001), *System and Method for Navigating in Virtual Environments Using a Fluid Model*, Serial Number 10/246.016.

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[13] Z. Liang, H. Lu, and X. Li (2002), *Noise Treatment System for Low-dose CT/ECT Medical Imaging Diagnosis*, Serial Number R-7519.

[14] Z. Liang, Z. Wang, and L. Li (2002), *Computer Aided Diagnosis by Mixture-based Image Segmentation, Texture Analysis, and Feature-based Volumetric Rendering*, Serial Number 60/358,305.

INVITED LECTURES:

Topic	*Conference & Location*	*Date*
Bayesian Image Modeling and Processing	6th Intl Conf on Math Modeling, St. Louis, MO	07/12/87
Bayesian Image Analysis	Applied Math Dept Seminar, Duke University, NC	02/22/88
The Physics of Medical Imaging	Electrical Engineering Dept Seminar, SUNY-SB, NY	10/21/92
Tissue Characterization by MR Images	Applied Statistics Seminar, Univ of Mass at Amherst	10/18/93
Quantitative Medical Tracer Imaging	Stochastic Modeling Workshop, SUNY-SB, NY	11/15/94
Quantitative Brain SPECT Reconstruction	Medical Dept Seminar, BNL, NY	03/06/96
Automating Brain Tissue Segmentation	Computer Science Dept Seminar, SUNY-SB, NY	03/07/97
Aspects of Automating image Segmentation	Tech Seminar, Medical Soft Inc., Boston, MA	01/23/98
Medical Imaging Informatics	Medical Informatics Dept, Columbia Univ, NY	02/12/98
Medical Imaging in Cardiovascular Research	Sino-USA Workshop on Biomedical Research, Boston	07/09/99
Quantitative Myocardial Perfusion SPECT	Radiology Dept, Harvard Medical School, Boston	07/13/99
Virtual Endoscopy for Cancer Detection	Medical Dept Seminar, BNL, NY	08/19/99
3D Image-Based Diagnosis and Treatment	Biomedical Engin Seminar, SUNY-SB, NY	11/03/99
3D Imaging in Diagnosis and Therapy	Nassau County Med Center, Long island, NY	02/25/00
Segmentation of MR images for MS Analysis	2001 MS Brain Atrophy/Surrogate Markers Summit, VA	03/30/01
MRI volumetric analysis on MS	2002 Summit – Clinical Issues and Decisions, GA	03/10/02
Medical Imaging Informatics	Grand Rounds, Department of Radiology, SUNY-SB	05/01/02

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Signature of Candidate

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Date

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Michael Robkin, MBA

Healthcare IT and Medical Device Executive

Michael Robkin has 30 years of Experience in Health Information Technology and Medical Devices. He has led the acquisition, development, and operation of EHRs, Clinical Information Systems, Ancillary Systems, Enterprise Systems, and Medical Devices for large Integrated Healthcare Systems. Mike has led research programs in Medical Device Interoperability, Security, and Patient Experience for both government and industry customers. He is a frequent speaker at conferences on Healthcare Interoperability and Cyber-security.

Michael Robkin, MBA

Woodland Hills, CA

Healthcare IT and Medical Device Executive

- 20 years of leadership experience in Healthcare IT, Medical Devices, International Business Development, Mission-Critical System Development, and Software Research.
- Comfortable with C-Level executives, government leadership, and all levels of clinical and technical SMEs.
- Deep expertise in the governance, acquisition, development, operations, integration, regulation, quality, and re-imbursement of HIT and Medical Devices.
- Worked for, and with, government agencies and some of the largest and most respected healthcare, manufacturing, and technology companies.

Professional Experience

Consultant and Small Business Owner, Woodland Hills, CA **2009 - Present**

Specialized HIT and Medical Devices market analysis and product development services. Customers include Massachusetts General Hospital, Intel, and the largest healthcare services company China.

- Acting Chief Engineer for new HIT and Medical Device integration platform product line. Responsible for defining product capabilities, budget, schedule, human resources, PKI, and tooling. Trained staff on project management, HIT standards, and engineering, software, and quality best practices. Negotiated clinical and business partnerships with EHR vendors and HDOs.
- Market, Product, Technology and Regulatory analysis of SaaS and Platform products for Fortune 500 clients.
- Technical lead and PI for Research Grants on Medical Device interoperability, safety, and cyber-security.
- Co-wrote and co-taught complete (44 course hour) Systems Engineering course for the Healthcare Industry harmonized with GMP and ISO 13485.
- Co-Chaired FDA Joint Workshop on Medical Device Interoperability: Achieving Safety and Effectiveness.
- Created and implemented Population Health/ACO HIT strategy for large US hospital chain.
- Created successful business development strategy for Gene Therapy start-up.
- Analyzed market opportunities, and then managed development of m-Health apps, utilizing both agile and waterfall software development life-cycles (SDLC).

Kaiser Foundation Hospitals, Pasadena & Oakland, CA **1997 - 2009**

Principal Enterprise Architect:

Lead Enterprise Architect responsible for technology and portfolio strategy for clinical ancillary systems such as Medical Imaging, Medical Devices, Pharmacy, Clinical Laboratory, and Pathology, including integration with KP HealthConnect. Forged productive collaborative relationships with business, physician, nursing, IT, and biomedical stakeholders.

- Led definition of key Business, Portfolio, Application, and Integration Enterprise Architectures. Collaborated with Data, Network, DR, and Security Architects, Clinical & Business stakeholders, and IT development and operations.
- Led KP's National Medical Imaging Architecture – at the time the largest single shared Medical Imaging architecture the world in terms of geography, network traffic, and data.
- Partnered with business, clinical, and IT stakeholders across 7 states and dozens of business units to define IT needs; collaborated on the acquisition and implementation of in-house, customized, and off-the-shelf solutions.
- Mentored design reviews of major Health IT projects to ensure compliance with Portfolio, Data, Security, Technology, SOA, and Integration Architectures.
- IT representative to KP's National Product Council. Responsible for achieving compliance with internal standards and architecture through influence and consensus-building with business and clinical stakeholders.
- Corporate Evangelist for clinical and patient safety through Medical Device and HIT Interoperability. Developed productive relationships with the VHA, the Army Medical Command, Partners Healthcare, and the FDA.
- Saved $30M CAPEX by identifying over-engineered and duplicate IT systems.

Continua Health Alliance, Portland, OR **2006 - 2009**

Board of Directors and Treasurer

- Help build Continua from conception to a thriving alliance of more than 200 international companies.
- Oversaw development of interoperability guidelines, software, and test & certification tools harmonized with government and international standards such as IEEE 11073 and IHE PCD.

Perceptronics, Woodland Hills, CA **1996 - 1997**

Perceptronics was a world-leader in large-scale distributed computing

Senior Systems Engineer

- Analyzed new business opportunities for technical feasibility.

Hughes International GmbH,, Rüsselsheim, Germany **1994 - 1996**

Hughes International managed all corporate, sales, and factory training for 30,000 employees of GM-Europe in 26 countries, including Opel, Saab, Chevrolet, Cadillac, and Vauxhall brands

Engineering Manager

- Developed a standard learning management system for 20 formerly silo-ed GM training divisions.
- Helped build consensus for our solution with multiple internal corporate silos and numerous service and consulting vendors across 9 countries.
- Formed a productive and respected team from scratch – every person in my group was from different countries.

Hughes Simulation Systems, Inc., Azusa, Fullerton, and Malibu, CA **1987 - 1994**

(formerly Honeywell, and now Raytheon)

Senior Systems & Software Engineer

- Research projects in distributed computing, network protocols, integrated software development environments and computer-generated imagery.
- End-to-end development of aircraft and other simulations. F16 product called "best in the industry" by our Air Force customer.

Education

Pepperdine University, Malibu, CA. President's and Key Executive MBA **2009-2011**

Harvey Mudd College, Claremont, CA. Systems Engineering **1983-1987**

Selected Awards, Presentations, and Peer-Reviewed Papers

- Senator Edward M. Kennedy Award for Healthcare Innovation, 2007. Awarded to the CIMIT Medical Device Plug and Play team.
- American Telemedicine Association's President's Award for Innovation, 2009. Awarded to the Continua Health Alliance.
- Plenary Speech: *A Short History of Interoperability*, FDA/CIMIT/Continua Workshop on Medical Device Interoperability: Achieving Safety and Effectiveness. January 26, 2010. Silver Spring, MD
- Invited Presentation: *Who's Watching the Wild, Wild, West: Regulatory Considerations*. AAMI–FDA Interoperability Summit Medical Device Interoperability: A Safer Path Forward. Oct 3, 2012. Wash., DC.
- *Levels of Conceptual Interoperability Model for Safe Medical Device Interoperability.* IEEE Symposium on Product Compliance Engineering (ISPCE). May, 2015. *Nominated for best conference paper.*
- *A Systems Engineering Approach to Risk Management*. AAMI/FDA Risk Management Summit. Sept., 2015

Professional Organizations

- Medical Device Plug-and-Play Program (www.MDPNP.org). Leadership Team.
- Open Health Tools – *merging with HL7.org.* Leadership Team.
- HIMSS (Health Information and Management Systems Society)
- INCOSE (International Council on Systems Engineering)
- AAMI (Association for the Advancement of Medical Instrumentation)

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, STAFF ATTORNEY
SUBJECT:	APPOINTMENT TO THE ADVISORY COMMITTEE ON CHILDHOOD CANCERS
DATE:	MAY 8, 2019

Summary and Recommendation

At its May 10th meeting, the Nominations subcommittee will discuss Presiding Officer Will Montgomery's proposed appointment to the Advisory Committee on Childhood Cancers (ACCC) and vote on whether to recommend that the Oversight Committee vote to approve the appointment.

Discussion

Texas Health and Safety Code Section 102.155 directs the Oversight Committee to create an advisory committee specifically related to childhood cancers. The ACCC reviews current information regarding innovative research on the prevention, control, and cure of childhood cancers and advises the Oversight Committee on issues surrounding childhood cancer. CPRIT's administrative rules dictate that the presiding officer of the Oversight Committee is responsible for appointing experts to serve on CPRIT's advisory committees. Appointments to the ACCC must be approved by the Oversight Committee.

The Nominations subcommittee will consider the pending ACCC appointment at its May 10th meeting.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Theodore W. Laetsch, MD**

eRA COMMONS USER NAME (credential, e.g., agency login): TLAETSCH

POSITION TITLE: Associate Professor, Division of Hematology/Oncology, UT Southwestern Medical Center

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Arizona, Tucson	BS (honors)	05/2001	Biosystems Engineering
University of California, San Francisco	MD	06/2005	Medicine
University of Colorado / Denver Children's Hospital		06/2008	Pediatric Residency
University of Colorado / Denver Children's Hospital		06/2009	Chief Residency
Children's Hospital of Philadelphia		06/2012	Heme/Onc Fellowship

A. Personal Statement

I am an Associate Professor of Pediatrics at the University of Texas Southwestern Medical Center / Children's Health Medical Center, Dallas. I lead both clinical and laboratory-based research evaluating novel therapeutics for high-risk pediatric cancers with an overarching goal of translating precision medicine approaches from the laboratory to the clinic. My fellowship work focused on identifying mechanisms to restore apoptotic signaling in neuroblastoma in the laboratory and led to a currently accruing phase I clinical trial in children with relapsed or refractory neuroblastoma. Currently, I am focused on targeted drug delivery and molecularly targeted therapies for pediatric cancer. I lead the experimental therapeutics program at the Children's Medical Center. I am active in pediatric early phase drug development nationally, having developed and opened two investigator initiated clinical trials "A Phase II Study of Sirolimus and Erlotinib in Recurrent/Refractory Germ Cell Tumors" (NCT01962896), and "MR-HIFU Hyperthermia with Liposomal Doxorubicin (DOXIL) for Relapsed or Refractory Pediatric and Young Adult Solid Tumors" (NCT02557854) based on preclinical work completed at UT Southwestern. I am the chair of the Rare Tumors Committee of the Children's Oncology Group, serve on the Pediatric NCI/COG MATCH Target and Agent Prioritization Committee, and am the principal investigator of the PI3K/mTOR arm of the Pediatric MATCH study.

B. Positions and Honors

Positions and Employment

2005-2008	Pediatric Resident, Denver Children's Hospital
2008-2009	Pediatric Chief Resident, Denver Children's Hospital
2009-2012	Fellow in Pediatric Hematology/Oncology, Divisions of Hematology and Oncology, Children's Hospital of Philadelphia
2012-2013	Instructor, Division of Oncology, Children's Hospital of Philadelphia
2013-Present	Assistant Professor, Division of Hematology/Oncology, UTSW Medical School
2014-Present	Leader of the Experimental Therapeutics Program, Children's Medical Center of Dallas, Pauline Allen Gill Center for Cancer and Blood Disorders

2015-Present	Co-director of the Protein Therapeutics and Tumor Microenvironment Theme in the Experimental Therapeutics Program, UT Southwestern Simmons Comprehensive Cancer Center
2018-Present	Associate Chair of the UT Southwestern Simmons Comprehensive Cancer Center Data Safety and Monitoring Committee

Honors and Achievements

1997	National Merit Scholar
1999-2001	Gold Headed Cane Society Tau Beta Pi Honor Society Alpha Epsilon Honor Society
2004	Alpha Omega Alpha
2005	Kaiser Award for Excellence in Teaching Nominee, University of California Essential Core Teaching Award Nominee, University of California
2008	Joseph W. St. Geme, Jr., M.D. Award for Outstanding Research as a Resident, University of Colorado
2012	CHOP Pediatric Scholar, Child Health Research Career Development Award (K12)
2012	Bear Necessities Pediatric Cancer Foundation Research Award
2013	CCCR-ALSF Young Investigator Research Award
2014	Children's Cancer Fund Research Award
2014	Micaela's Army Foundation Research Award
2015	Rally Foundation for Childhood Cancer Research Award
2016	Early Career Investigator Award Cold Spring Harbor, 2016 Special Conference on Pediatric Clinical Oncology. CAC2 - From Bench to Bedside and Beyond.
2018	UT Southwestern Leaders in Clinical Excellence Awards - Rising Star Award
2019	Norma and Jim Smith Professorship of Clinical Excellence
2019	Eugene P. Frenkel, M.D. Scholar in Clinical Medicine

Specialty Certification and Licensure

2008-present	Diplomat of the American Board of Pediatrics
2012-present	Board Certification in Pediatric Hematology / Oncology
2013-present	Texas Medical License

Professional Memberships

2005	Member and Program Delegate (2007, 2008), American Academy of Pediatrics
2009-present	Member, American Society of Pediatric Hematology/Oncology
2009-present	Member, Children's Oncology Group
2010-present	Member, American Society of Clinical Oncology
2010-present	Member, American Association for Cancer Research
2015-present	Member, Pediatric MATCH Target and Agent Prioritization Committee
2016-present	Member, COG NCI Pediatric MATCH Leadership Committee
2016-present	Member, International Society of Paediatric Oncology (SIOP)

C. Contribution to Science

1. MR-HIFU for Pediatric Sarcomas

In collaboration with Dr. Rajiv Chopra, a physicist at UTSW, I co-lead an R01 focused on evaluating the ability of MR-guided High Intensity Focus Ultrasound (MR-HIFU) to increase the efficacy and decrease the toxicity of liposomal chemotherapeutics. In the laboratory, we demonstrated that MR-HIFU can precisely deliver heating to tumor with sufficient precision for the clinical delivery of hyperthermia by the use of drift correction algorithms that limit the effect of changes in the MRI's magnetic field over time. Further, we identified a novel method of MR based temperature measurement in cortical bone that may expand the anatomic locations treatable by this technique Combining MR-HIFU hyperthermia with thermosensitive liposomes, we have shown augmentation of the intratumoral doxorubicin concentration by greater than 4-fold without an increase cardiac doxorubicin concentrations Translating this to the clinic, I have shown that

the majority of pediatric sarcomas are anatomically targetable by MR-HIFU at diagnosis Based on this work, I opened and secured an IND for the first-in-kids clinical trial of MR-HIFU hyperthermia with liposomal doxorubicin (NCT02557854).

a. E Ramsay, C Mougenot, M Kazem, **TW Laetsch**, R Chopra. Temperature-dependent MR signals in cortical bone: Potential for monitoring temperature changes during high-intensity focused ultrasound treatment in bone, Magn Reson Med, 2015 Oct;74(4):1095-102.
b. C Bing, R Staruch, M Tillander, MO Köhler, C Mougenot, M Ylihautala, **TW Laetsch**, Chopra R. Drift correction for accurate PRF shift MR thermometry during mild hyperthermia treatments with MR-HIFU. International Journal of Hyperthermia. 2016 May 22:1-15
c. J Shim, RM Staruch, K Koral, XJ Xie, R Chopra, **TW Laetsch**. Pediatric Sarcomas Are Targetable by MR-Guided High Intensity Focused Ultrasound (MR-HIFU): Anatomical Distribution and Radiological Characteristics. Pediatric Blood and Cancer. 2016 Oct;63(19):1753-60.

2. Molecularly Targeted Therapy for Pediatric Solid Tumors

I am actively studying the efficacy of personalized therapy based on tumor genomics, independent of histology, for children with refractory solid tumors. In collaboration with Loxo Oncology, I led the pediatric development of larotrectinib, the first highly selective inhibitor of the TRK kinases to reach the clinic in collaboration. In our recently reported analysis of the first 55 children and adults with TRK fusion positive cancers treated with larotrectinib, we found a 75% centrally confirmed overall response rate. Demonstrating the promise of highly selective drugs to target a biomarker across tumor types, responses appeared independent of the 17 different tumor types with which patients enrolled on study. Remarkably, acquired resistance to therapy was rare and the median duration of response has not yet been reached. This data formed the basis for the New Drug Application (NDA) for larotrectinib. Among the 12 pediatric patients on this study, all had NRSTS as will be studied here.

In addition to these efforts leading the development of molecularly targeted inhibitors for biomarker defined pediatric patients, I have collaborated on large scale efforts to evaluate the genomics of pediatric cancers. Looking at over 80,000 children and adults who had their tumors analyzed by next generation sequencing, we demonstrated that different patterns of hypermutation resulting from both germline and somatic events can be distinguished for individual patients from somatic sequencing data and that these drivers can predispose to response to immunotherapy.

a. **TW Laetsch*,** SG DuBois*, R Nagasubramanian, B Turpin, L Mascarenhas, N Federman, M Reynolds, S Smith, S Cruickshank, MC Cox, A Pappo, DS Hawkins. Larotrectinib (LOXO-101) for Pediatric Solid Tumors Harboring NTRK Gene Fusions. Lancet Oncology. 2018 Mar 29.
b. A. Drilon*, **T.W. Laetsch* (contributed equally)**, S. Kummar, et al. Efficacy of Larotrectinib in TRK Fusion–Positive Cancers in Adults and Children. *New England Journal of Medicine*. 2018 Feb 22; 378
c. BB Campbell, N Light, D Fabrizio, …, **TW Laetsch**, et al. Comprehensive Analysis of Hypermutation in Human Cancer. *Cell*. 2017 Oct 18.

3. CAR T-Cell Therapy for Pediatric Leukemia

Chimeric antigen receptor T-cell (CAR-T) therapy is a novel genetically engineered immunotherapy in which a patient's own T-cells are removed from the body, transduced with a lentivirus causing expression of a chimeric antigen receptor targeting their cancer, and then reinfused into the patient. I led the study of CAR-T for children with relapsed leukemia at UTSW as one of only 13 sites across the US that conducted this clinical trial. Our study demonstrated that CAR-T therapy to be highly active, inducing remission in 83% of patients, while historically the best available therapies induce remission in less than 50%. We also showed that while this therapy is both logistically complex and carries a risk of severe toxicities including cytokine release syndrome, it was feasible to administer CAR-T cell therapy to children on 4 continents. This data resulted in FDA approval of CAR-T therapy for children with relapsed and refractory leukemia, the first gene therapy approved by the FDA for any condition. My work is now focused on extending the range of diagnoses treatable by CAR T-cell therapy through a UTSW funded collaboration with Dr. Alec Zhang on a novel AML CAR T-cell target, and studying novel methods of CAR-T cell manufacture in an effort to substantially reduce the cost and time required for manufacture CAR-T in collaboration Dr. Caroline Lux.

a. SL Maude, **TW Laetsch**, J Buechner, et al. Tisagenlecleucel in Children and Young Adults with B Lymphoblastic Leukemia. *New England Journal of Medicine*. 2018 Feb 1; 378:439-448

b. **TW Laetsch**, SL Maude, MC Milone, et al. False-Positive Results Following Lentiviral-Based Tisagenlecleucel Therapy with Select HIV-1 NAT Methods. *Blood*. 2018; 131(23):2596-2598.

4. Novel Therapies for Neuroblastoma

My fellowship work focused on identifying mechanisms to restore apoptotic signaling in neuroblastoma. Many cancer cells have tonic pro-apoptotic signaling, but have activated anti-apoptotic mechanisms to prevent cell death. Blocking these anti-apoptotic mechanisms can restore apoptotic signaling in cancer cells with minimal toxicity in normal cells that are not primed for death. Using an siRNA screen, I identified PRPF8 and UBL5, both components of the spliceosome that regulate apoptotic signaling in neuroblastoma by alternative splicing of the anti-apoptotic protein MCL1 into a pro-apoptotic isoform. Using small molecule inhibitors, I demonstrated efficacy of spliceosome inhibition in xenograft models of neuroblastoma (Spliceosome inhibitors are now being advanced toward the clinic and this work provides rationale for clinical trials in neuroblastoma and further preclinical study in the multitude of cancers dependent on MCL1. Additionally, our team found that polyamine antagonism using celecoxib and DFMO blocked tumor initiation and was able to regress established xenograft models of neuroblastoma (This work had led to an open New Approaches to Neuroblastoma Therapy (NANT) consortium phase I study of DMFO and celecoxib in combination with cyclophosphamide and topotecan that is currently recruiting patients (NCT02030964).

a. **TW Laetsch**, X Liu, A Vu, M Sliozberg, M Vido, OU Elci, KC Goldsmith, and MD Hogarty. Multiple components of the spliceosome regulate Mcl1 activity in neuroblastoma. Cell Death and Disease. 2014 Feb 20;5:e1072.

b. NF Evageliou, M Haber, A Vu, **TW Laetsch**, J Murray, LD Gamble, NC Cheng, K Liu, M Reese, KA Corrigan, DS Ziegler, HT Webber, CS Hayes, BR Pawel, GM Marshall, H Zhao, SK Gilmour, MD Norris, MD Hogarty. Polyamine antagonist therapies inhibit neuroblastoma initiation and progression. Clinical Cancer Research. 2016; 22(17):4391-404.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/browse/collection/49122211/?sort=date&direction=ascending

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D. Research Support

Ongoing Support

- NIH R01 CA199937 (Co-PI: Laetsch, Chopra) 7/1/2015-6/30/2020
  Image-guided Doxorubicin Delivery for Pediatric Sarcomas
  This grant will evaluate and optimize Magnetic Resonance guided High Intensity Focused Ultrasound (MR-HIFU) guided thermosensitive liposomal doxorubicin delivery for pediatric sarcomas. Using pre-clinical models, this effort will determine the optimal heating duration and liposomal doxorubicin dose that maximizes the therapeutic ratio of drug accumulation in the tumor to that in normal tissue including the heart, evaluate the efficacy of this technique in a model of Ewing's sarcoma, and evaluate the ability of novel techniques for bone thermography to expand the anatomic locations treatable by MR-HIFU.

- NIH U54 CA196519, Project 2 (PI: Skapek, Role: Co-Investigator) 9/1/2015-8/31/2020
  Developmental and Hyperactive RAS Tumor Spore
  Project 2 of this SPORE focuses on identifying new therapies and biomarkers of therapy response in Malignant Peripheral Nerve Sheath Tumors (MPNST). Existing data has demonstrated benefit of CDK4/6 and CXCR4 inhibition in preclinical models of MPNST. In this project, using a murine MPNST model, the relationships of between intratumoral and serum pharmacokinetics, target inhibition, and response to treatment will be evaluated. Second, the utility of FLT-PET as an early biomarker of response will be studied in preclinical models. These preclinical studies will inform phase 0 studies of these agents in patients with MPNST led by Dr. Laetsch.

- US DEPARTMENT OF DEFENSE (PI: Lux, Role: Co-Investigator) 07/01/17-06/30/19
  Eliminating ex-Vivo Manipulation and Viral Transfection of T-Cells in CAR-T Cell Immunotherapy of B-Cell Malignancies
  The goal of this grant is to prove feasibility, and, equally important, define potential limitations, such as transfection efficiency *in vivo* under flow conditions and longevity of CAR expression to better guide development of CAR T-cell manufactured *in vivo* using ultrasound-based transduction.

- NIH U10 CA180886 (PI: Adamson, Role: Study Chair) 03/01/18-2/28/19
  MATCH COMMITTEE-NIH National Clinical Trials Network (NCTN) Grant
  This grant supports Dr. Laetsch's effort as the PI of the PI3K-mTOR arm of the NCI/COG Pediatric MATCH study. The primary objective of this study is to determine the objective response rate to the PI3K/mTOR inhibitor LY3023414 in children whose tumors harbor mutations that are predicted to activate this pathway.

Michelle Barton, Ph.D. – Biographical Sketch

Michelle Barton was born at Fort Sam Houston, San Antonio, TX but spent the vast majority of her childhood on a small family farm in Illinois. She went to the University of Illinois-Urbana, as the first in her family to go to college and received her BS in biochemistry. After working as a research assistant at the Boston University Medical School, she returned to University of Illinois and entered graduate school. She received her PhD in Biochemistry, working with Dr. David Shapiro in the field of estrogen regulation of gene expression. Dr. Barton went to San Diego for her postdoctoral studies in the field of epigenetics with Dr. Beverly Emerson at The Salk Institute for Biological Studies. These studies were supported by fellowships from the Anna Fuller Foundation and an NIH National Research Service Award. Dr. Barton's first faculty appointment was at the University of Cincinnati Medical School, where she was promoted to tenured Associate Professor. Soon after, she was recruited to the UT MD Anderson Cancer Center in 2000. At MD Anderson, she is a full professor in the Department of Epigenetics and Molecular Carcinogenesis and the Colin Powell Chair for Cancer Research. In 2012, she became the MD Anderson Dean of the UT MD Anderson Cancer Center UTHealth Graduate School of Biomedical Sciences

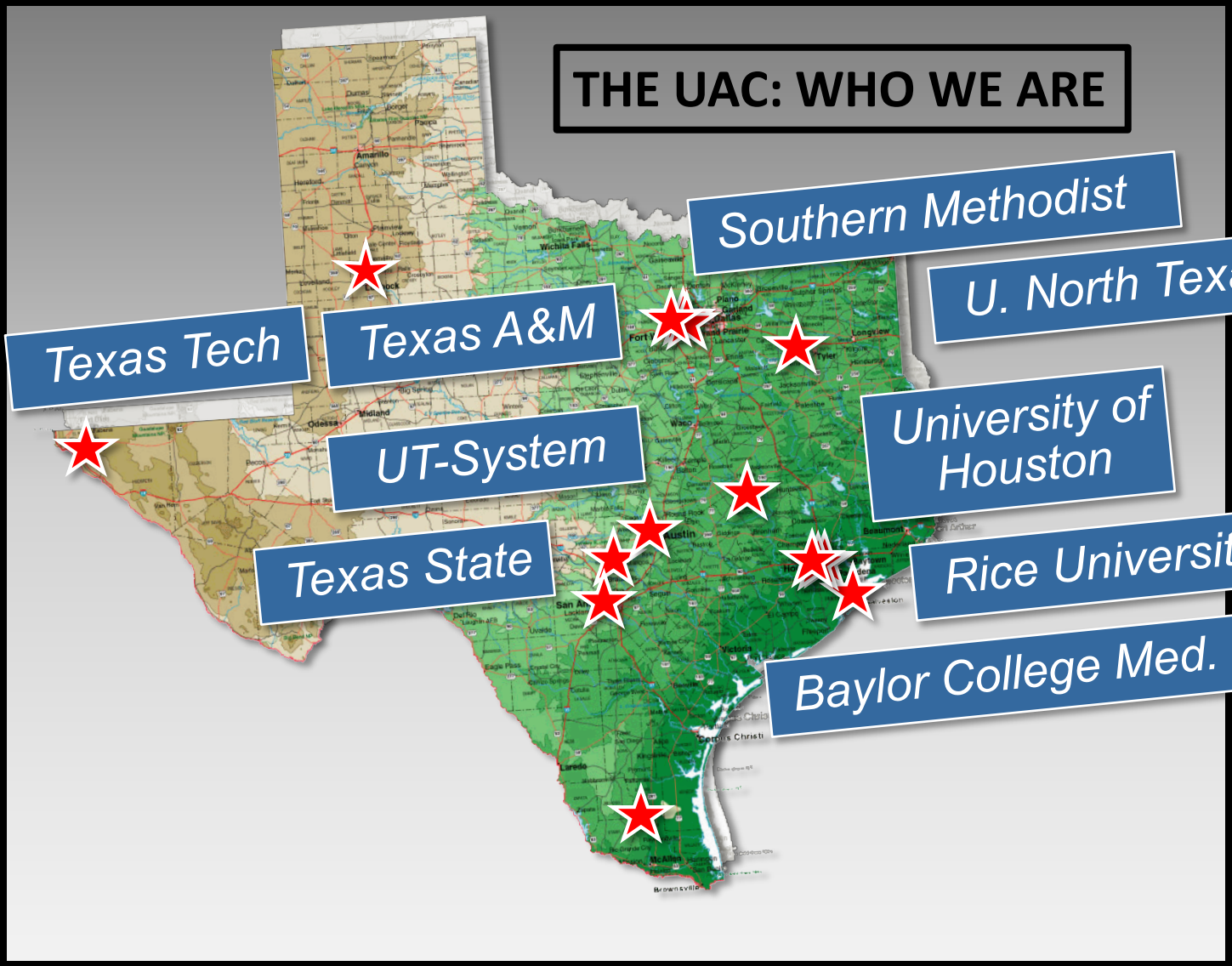
2018 UAC Annual Report

CPRIT University Advisory Committee Annual Report

Presented to the CPRIT Oversight Committee May 15, 2019

Chair: Michelle Barton, PhD – UT MD Anderson Cancer Center

Vice-chair: C. Kent Osborne, MD – Baylor College of Medicine


THE UAC: WHO WE ARE
Southern Methodist
U. North Texas
Texas Tech
Texas A&M
University of Houston
UT-System
Texas State
Rice University
Baylor College Med.

Background

- The mission of the University Advisory Committee (UAC)

  "Advises the UOC on the role of higher education in cancer research. The members of the UAC include representatives of Texas public university systems and private research universities."

Background

- The focus of the University Advisory Committee (UAC)

  How has CPRIT impacted cancer research across Texas?

  What are the most effective mechanisms of CPRIT funding?

  What priorities support a sustained impact for Texas?

  How can we help assure cancer research continues to thrive in Texas?

Academic Research Program Priorities: 2019

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research
- Implement research and deployment of evidence-based prevention and screening interventions
- Computational biology and analytic methods
- Childhood cancers
- Population disparities and cancers of importance in Texas: Hepatocellular cancer and obesity-linked cancers

UAC Recommendations for 2019

- Improve information and communication on ROI to the public
  - Improve the CPRIT website
  - Highlight how CPRIT investment has impacted our state's underserved population and what measures will be taken to increase this impact

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Home | Our Programs | Apply for Funding | Grants Funded | Grants Process | News & Events | About Us

Home > News & Events > Announcing CPRIT's New Website and 2018 Annual Report

Announcing CPRIT's New Website and 2018 Annual Report

Published: February 01, 2019

Yesterday I delivered CPRIT's 2018 Annual Report to state leadership and the Texas Legislature. It can be accessed here on CPRIT's new website.

This new website is a platform for sharing news and information on CPRIT's investments and advances in cancer research, product development and prevention. The newsroom features our grantees and current CPRIT events, with access to our social media channels. New features include sections on CPRIT's impact, greater detail on CPRIT Scholar recruitments and CPRIT-funded core facilities at Texas' academic institutions. Also available are current reports used to inform the public, legislators and media.

News & Events

Media Resources

Logo & Brand Standards

Reports

Webinars

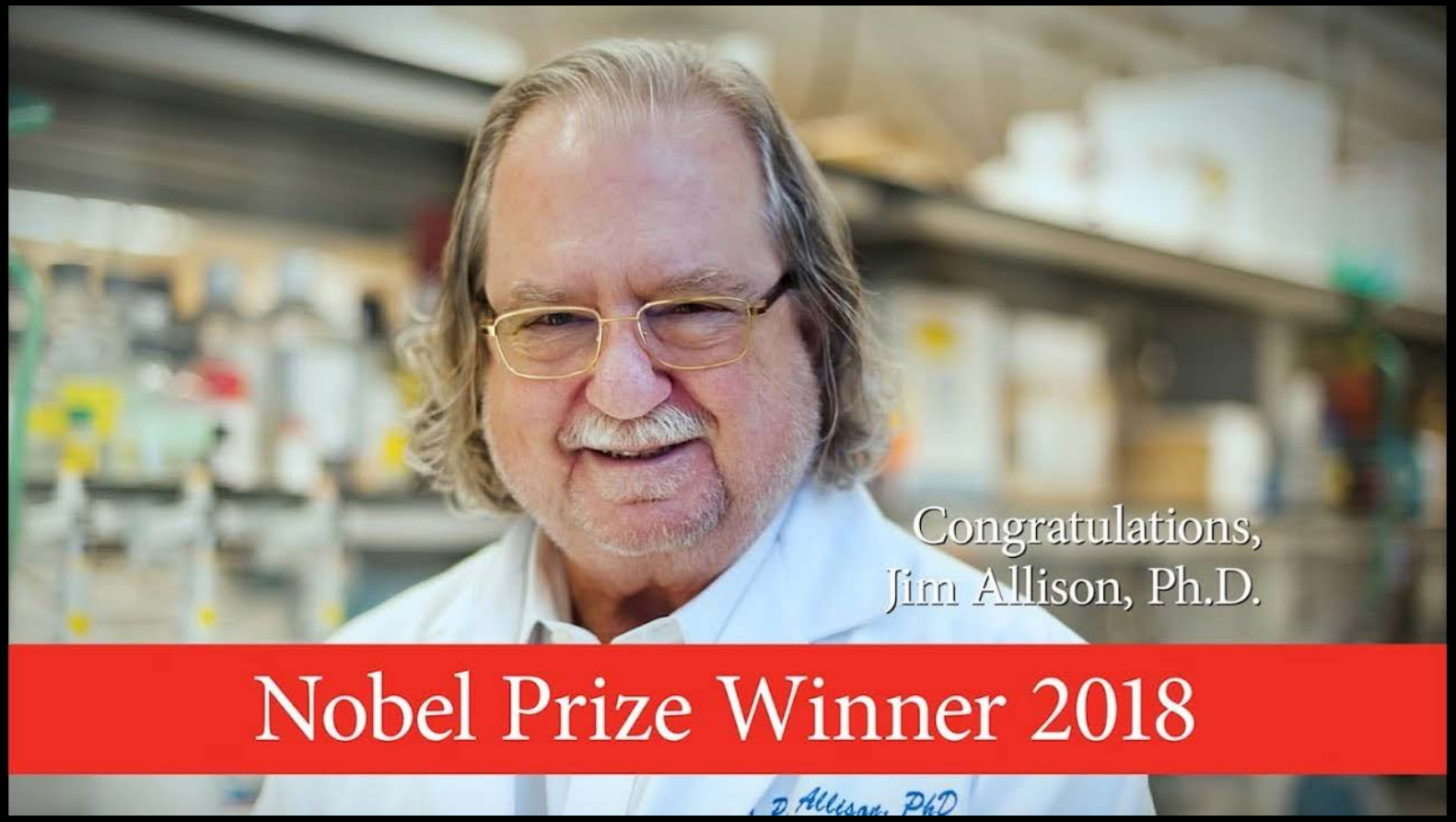
Follow-on funds **($2.6 Billion)** for the two research programs **($1.8 Billion)**, exceeding contracted awards by **$804 M**

Last Updated: August 31, 2018

Real Momentum, Measurable Results:
Investing in Texas Research Capabilities

159 CANCER RESEARCHERS and their labs recruited to Texas

With CPRIT funding, Texas is well on its way to having the finest cluster of cancer researchers in the world.


Congratulations,
Jim Allison, Ph.D.
Nobel Prize Winner 2018

43 Core Facilities

supported to ensure cutting-edge research

CPRIT's investment in core facilities fosters collaboration among cancer researchers and provides shared access to current technology.

108 New Clinical Studies

CPRIT funding has resulted in the enrollment of 13,318 patients in clinical studies.

132 CHILDHOOD & ADOLESCENT cancer projects supported by CPRIT

CPRIT investment has made Texas a national leader with 12 percent, which is three times the national rate, of CPRIT's research portfolio going to childhood cancer research.

4.7 MILLION prevention services in Texas

Saving Lives: CPRIT funding has provided prevention services to Texans in all 254 counties.

CPRIT Impact by Mechanism

Funding Mechanism	# Awards	*Funding Amount	Number of Patents submitted, pending or issued	Number of Peer Reviewed Publications	Follow-on Funds
Scholars	171	$ 505,970,000.00	72	1022	$ 264,449,771.00
Core Facilities Support Awards	43	$ 187,740,000.00	28	271	$ 221,100,750.00
Shared Instrumentation	8	$ 12,440,000.00	0	66	$ 35,277,984.00
Early Translational Research Awards	36	$ 48,860,000.00	68	49	$ 13,225,868.00
High Impact/High Risk Awards	148	$ 29,530,000.00	56	166	$ 25,134,713.00
Individual Investigator Research Awards	438	$ 427,017,814.00	184	1596	$ 255,941,615.00
Multi-Investigator Research Awards	206	$ 277,650,000.00	54	858	$ 143,164,834.00

Data through August 31, 2018

UAC Recommendations: Prioritizing Successes

1. Continue the successful CPRIT Recruitment Program: bringing the best of the best in cancer research to Texas

2. Continue to support the successes of Individual Investigator and Core Facility awards

3. Support the next generation of Cancer Researchers: Research Training awards

4. Support emerging Cancer Research across Texas through these mechanisms and High Impact/High Risk research awards

5. Decrease emphasis on Multi-Investigator research awards

UAC Recommendations: Outward looking

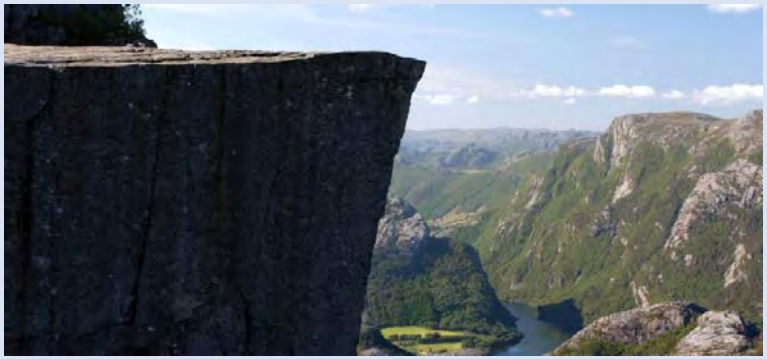
1. Continue support of efforts to fight liver cancer across Texas and especially in the Rio Grande Valley: Collaborative Action Program to reduce liver cancer mortality in Texas

2. Bring access to cutting-edge cancer clinical trials to all residents of Texas: Proposal to Increase Access to Clinical Trials and Expand Clinical Trial Accrual in Texas

3. Texas has increase NCI Comprehensive Cancer Centers from 1 to 3 via CPRIT initiatives. Can we do more across the state?

HAG Presentations – CBIIT Funding models

Real Momentum, Measurable Results:
Expediting Innovation in Cancer Prevention and Cures



2018 UAC Annual Report

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Presented to the CPRIT Oversight Committee May 15, 2019

Chair: Michelle Barton, PhD – UT MD Anderson Cancer Center

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CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

University Advisory Committee 2018 Annual Report

Membership Roster

Michelle C. Barton, Ph.D.
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Vice Chair, 2016-2018
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Professor, Epigenetics & Mol. Carcin.
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2018-9 UAC Meetings
The CPRIT University Advisory Committee (UAC) worked closely with Dr. Willson and the CPRIT Office to continue building upon the accomplishments of CPRIT-funded cancer researchers to serve the citizens of Texas. The CPRIT UAC met as a full committee with members present by conference call or in person on three occasions:
April 26, 2018 – conference call and CPRIT conference room
October 10, 2018 – conference call and CPRIT conference room
February 25 2019 – conference call and MD Anderson Cancer Center conference room

April 26th meeting
Academic Research Program Updates and Planning: Dr. Willson provided a high-level review of FY18.1 award data, Cycle 18.2 submission data and Cycle 19.1 RFAs. Dr. Willson discussed the release of a modified Early Translational Research Award (ETRA) and Product Development Seed Award RFAs. He detailed the modifications made to the former ETRA RFA and introduced the new SEED award mechanism. Members expressed enthusiasm for both awards and encouraged the inclusion of Tech Transfer Offices in the application process. Dr. Willson stated the proposed institutional limits for application submissions and welcomed input from members on the proposed institutional limits.

A conceptual model of the Collaborative Action Program to reduce liver cancer mortality in Texas was discussed. Dr. Willson noted that CPRIT is hosting a meeting on May 1, 2018 with representatives from Academic Institutions across Texas to discus and further delineate the conceptual model.

October 10th meeting
Dr. Barton opened the meeting by congratulating Mr. Wayne Roberts, CPRIT CEO, on receiving the Texas State Agency Business Administrators' Association (TSABAA) Administrator of the Year Award. Mr. Robert's thanked the Committee for their congratulations and for the continued support of CPRIT.

Mr. Robert's provided an overview of CPRITs reauthorization process and encouraged members to speak to their Legislatures regarding the impact CPRIT has had on their Institutions. A Committee member suggested that the University Advisory Committee write an op-ed piece regarding the impact of CPRIT from Academic Universities point of view. [Note, an Op-Ed piece was written by Drs. Osborne and Barton and submitted for publication to Public Relations departments of Baylor and MD Anderson for submission to the Houston Chronicle. Submission was completed but, to date, no publication has appeared.]

Academic Research Program Updates and Planning: Dr. Willson provided a review of Fiscal Year 2018 award data, mentioning that all grants proposals recommended by the CPRIT Scientific Review Panels were awarded. He reviewed data on applications received and funds requested for Cycle 19. Dr. Willson discussed the Announced RFAs for FY2019, which include FY2019 Recruitment Award and Cycle 19.2. He highlighted a modified Early Translational Research Award (ETRA) RFA, detailing the modifications and purpose. Dr. Willson discussed progress on the Collaborative Action Program to reduce liver cancer mortality in Texas, which addresses an important need for Texans.

Dr. Willson reviewed the FY2019 Academic Research Program Priorities and a draft of the Academic Research Program RFA Release Schedule for FY2020-2021. He requested input from Committee members on the draft RFAs, noting a significant decrease in funds in Fiscal Years 2020 and 2021. Committee members prioritized Recruitment and Core Facility Support Award RFAs. Committee members also

requested return on investment data as a metric for assessing what RFAs to recommend for FY2020 and FY2021. [Note: CPRIT sent return on investment data, calculated for each funding mechanism, to members on October 12, 2018.] Drs. Osborne and Willson discussed the composition and purpose of the CPRIT Clinical Trials Advisory Committee.

February 25th meeting

Dr. Kent Osborne provided an update on CPRIT's Clinical Trials Advisory Committee recommendations that focus on:

- Development of a recruitment and career development program for clinical faculty at the Assistant Professors level whose focus is on clinical investigation. The program would protect a minimum of 50% time for research and include training components similar to the NIH Institutional Research Career Development K12 grant mechanism.
- Development of a CPRIT mechanism that will increase access and participation of under-represented populations in innovative clinical trials. The proposal was distributed for committee discussion and enthusiastically endorsed.

Academic Research Program Updates: Dr. Willson drew members' attention to data tables presenting: FY2018 award data; FY2019 Cycle 19.1 award data; FY2019 Cycle 19.2 submission data. Additionally, longitudinal award and impact data by CPRIT mechanism, as reported by grantees in their annual progress reports, was discussed.

RFA Mechanism Opportunities and Research Program priorities were discussed with regard to the planned RFA release schedule for FY 2020 and proposed for discussion potential RFAs for FY2021. Committee members discussed RFA priorities given the current budgeted allocation to Research and discussed RFA priorities in the event the Legislature approves the exceptional item funding for CPRIT.

The UAC recommends:

- CPRIT Recruitment Program (Scholars RFAs), Individual Investigator Research Award mechanism(s), Core Facility Support Awards, and High Impact/High Risk Research Award continue as the essential components of the research program grant portfolio.
- Committee members raised concern that the Multi-Investigator Research Award (MIRA) mechanism has not led to new NIH program project awards or SPORE grants and therefore should not be given precedence over other mechanisms particularly in the event the exceptional item is not approved.
- Opportunities to build and expand research capabilities at universities in all regions of the state. Committee members discussed strategies to increase CPRIT- and NCI-funded cancer research at Texas institutions that to date have not received significant CPRIT funding.

Further discussion focused on potential, new RFA mechanisms designed to support development of centers of excellence in a focused area of cancer research, which would build on an existing area of research or one that the institution had identified and planned to invest in as an opportunity. All agreed that any new initiative to develop focused Centers of Excellence must meet rigorous scientific review.

Two examples of mechanism used by the NIH to support centers of excellence at institutions without large NIH research portfolios were discussed; (1) The NIH Centers of Biomedical Research Excellence (COBRE) and (2) R15 Research Enhancement Award Program (REAP). The UAC encouraged CPRIT, as a funding entity, to consider

development of a similar model to build and expand cancer research capacity at institutions with modest CPRIT funding. Another strategy discussed would be a CPRIT mechanism to support partnerships with a Texas NCI Comprehensive Cancer Center to leverage research and technical capacity.

CPRIT's 2018 Annual Report was distributed to all members.

Next steps: The Committee will meet next in June 2019 as a teleconference to finalize recommendations for RFA recommendations for FY20 and 21, as the results of CPRIT funding bills before the 86th Legislature will be known at that time.

C. Kent Osborne, MD - Biographical Sketch

Dr. C. Kent Osborne was born in 1946 in St. Louis, Missouri. He received his AB and MD degrees from the University of Missouri, both with honors. He completed his internship and residency at Johns Hopkins Hospital in 1974, and then spent three years as a clinical associate at the Medicine Branch, Breast Cancer Section of the National Cancer Institute in Bethesda, Maryland. In 1977, he took his first faculty position at The University of Texas Health Science Center at San Antonio, where he rose to the rank of Professor and became Director of the Division of Medical Oncology in 1992. In 1999 Dr. Osborne and his team moved to Baylor College of Medicine to develop a new multidisciplinary Breast Center and in 2005 he was named Director of the new Dan L Duncan Cancer Center at Baylor College of Medicine which achieved **"comprehensive"** designation under his leadership in 2015.

Dr. Osborne is a physician scientist who has focused on breast cancer his entire career. His research interests include understanding the biology of breast cancer and then developing new treatment approaches for the disease. He has published extensively on the mechanisms by which hormonal therapies such as tamoxifen inhibit breast cancer growth and how breast cancers become resistant to these therapies. He has also studied the role of various growth factors in breast cancer development and progression, and more recently how these other growth factors can interact with estrogen to stimulate tumor growth. His laboratory is also focusing on the mechanisms by which breast cancers develop resistance to HER2-targeted therapies. For more than a decade Dr. Osborne was Chairman of the Breast Cancer Committee for the Southwest Oncology Group, where he directed numerous nationwide clinical trials investigating new treatment strategies for breast cancer patients. He was the Principal Investigator of the Baylor Breast Cancer Specialized Program of Research Excellence grant 26 years.

Among his previous awards are the Komen Foundation Award, the Brinker International Award for Breast Cancer Research, the European Institute of Oncology Annual Breast Cancer Award, and the ASCO Bonadonna Award for Breast Cancer Research. **Most recently, he received the 2018 AACR Distinguished Award for Extraordinary Scientific Achievement and Leadership In Breast Cancer Research.**

At Baylor College of Medicine, he is the Director of the Dan L Duncan Comprehensive Cancer Center and Professor of Medicine and Molecular and Cellular Biology. He currently holds the Tina and Dudley Sharp Chair in Oncology at Baylor College of Medicine.

Clinical Trials Advisory Committee: Annual Report

CPRIT Oversight Committee Meeting
May 15, 2019

C. Kent Osborne, Chair

Baylor College of Medicine

DAN L DUNCAN COMPREHENSIVE CANCER CENTER

NCI Designated Comprehensive Cancer Center

Baylor College of Medicine

DAN L DUNCAN COMPREHENSIVE CANCER CENTER

Clinical Trials Advisory Committee (CTAC)

Membership

- **C. Kent Osborne, MD**, Dan L Duncan Comprehensive Cancer Center, BCM
- **Ruben Mesa, MD**, Mays Cancer Center, UTHSCSA
- **Carlos Arteaga, MD**, Harold Simmons Comprehensive Cancer Center, UTSWMC
- **Stephen Eck MD, PhD**, Immatics US, Inc.
- **S. Gail Eckhardt, MD**, Livestrong Cancer Institute, DMC, UT Austin
- **David S. Hong, MD**, UTMDACC
- **C. Patrick Reynolds, MD, PhD,** Cancer Center, TTUHSC
- **Ray Tabibiazar, MD,** Aravive Biologics

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CTAC Meetings

1. **May 7, 2018:** Committee charge; review of current CPRIT investments
2. **Sept 18, 2018:** Reviewed potential solutions and principles CPRIT might consider
3. **Jan 21, 2019:** discussed specific proposals to recommend

10-4

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Targeted Therapy for Cancer (Precision Medicine)

1. Cancer is caused by **mutations in normal genes** which alter their functions in the cell
2. Many genes if broken or mutated can **cause cancer**
3. Particular set of mutations in a person's tumor **drives the cancer** to grow and spread
4. No two cancers are **exactly alike** genomically
5. Blocking the function of these mutant genes is a new **treatment strategy**
6. Determine which genes or pathways are malfunctioning then pick a **specific drug** to block
7. Requires **many new drugs** that target the function of these mutant genes

10-5

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Problems Implementing Precision Cancer Medicine

1. **Matching drug** with defective gene pathway
2. **Many potential mutations** require many new drugs
3. **Hundreds** of new drugs in pipeline
4. Only **5%** of all cancer patients in U.S. go on clinical trials
5. **Not enough patients** to rapidly evaluate exciting new drugs
6. Access to clinical trials limited to **academic centers** in larger metropolitan areas
7. **Lack of access** by patients in rural or underserved areas

10-6

Baylor College of Medicine

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Principles Recommended by CTAC

1. Increases access to clinical trials for patients in outlying areas/underserved
2. Competitive RFA process
3. Early phase trials that can be completed quickly
4. Investigator initiated trials derived from work in a Texas lab
5. Efficiency and speed
6. Partner with industry
7. Provide personnel and infrastructure to smaller hospitals

10-7

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Principles con't

8. Leverage infrastructure in the major cancer centers (CTSU, Core facilities)
9. Funding for tumor and blood biopsies for genomics for patient selection and research
10. Emphasize multi-institutional trials and collaborative studies

10-8

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Potential Solutions

1. Increase number of patients available for clinical trials
2. Expand access to rural or underserved areas
3. Provide clinical trial infrastructure and staff in outlying hospitals and clinics
4. Form a network to extend expertise in academic centers to outlying areas
5. Train more doctors with expertise in clinical trials; give them time to do clinical trial research

10-9

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Proposal 1: Increase Access to Clinical Trials

1. Create clinical trial networks
2. Hub and spoke model with major research institution (LI) partnering with outlying and/or underserved hospitals (NH)
3. Provide resources to LI to administer and coordinate a network, and
4. Resources to NH to create functioning clinical trials infrastructure

10-10

Clinical Trials Network Model

Baylor College of Medicine

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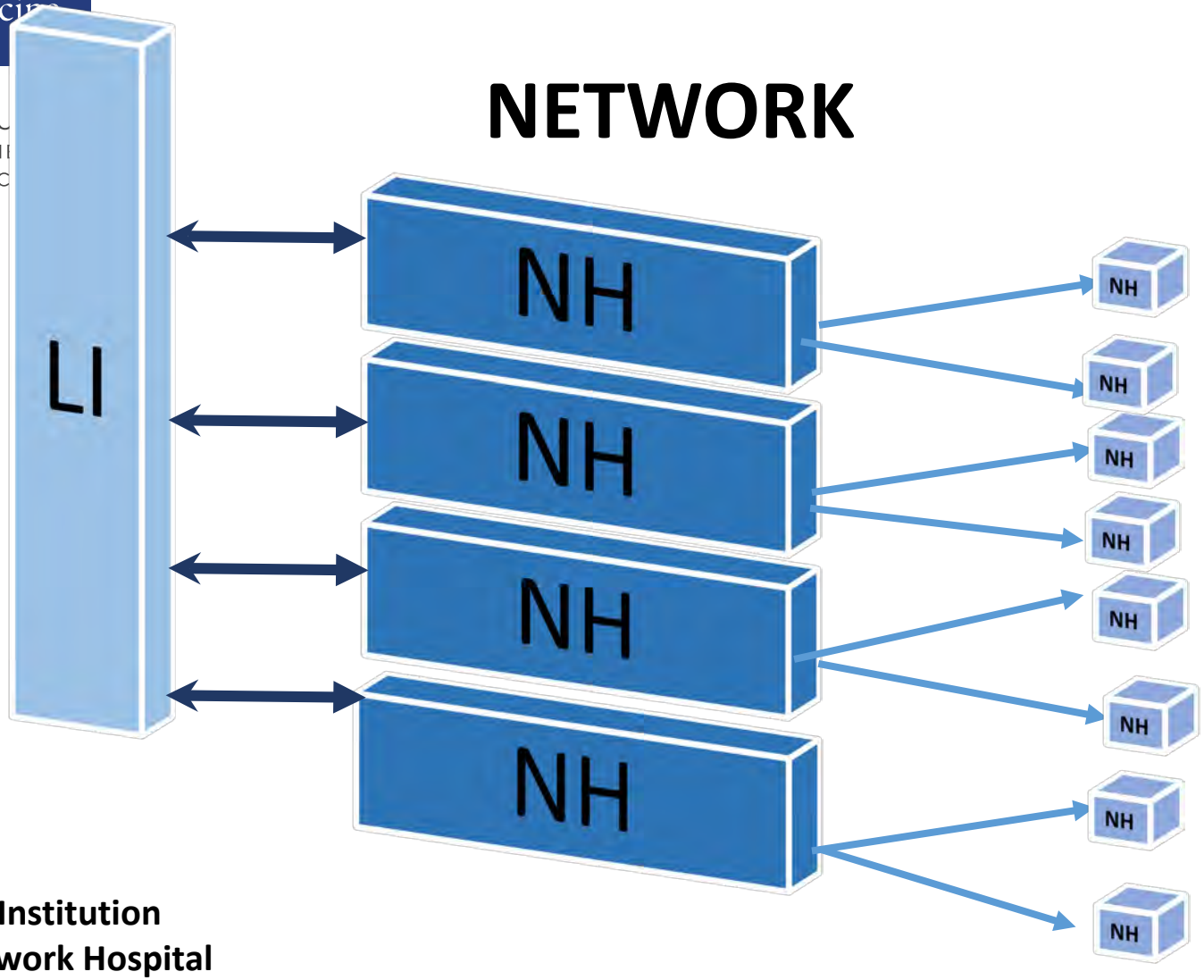

LI = Lead Institution
NH = Network Hospital

10-11

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Resources Needed (NH)

1. Research pharmacy
2. Research nurse
3. Study and regulatory coordinators
4. IRB fees for central IRB
5. Clinical trials monitoring system (OnCore)
6. Equipment for storing samples
7. Video conferencing capability
8. Funding for tissue biopsies for research
9. Salary support for physician champion
10. Funding for training of personnel and site visits

10-12

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Resources Needed (LI)

1. Incremental costs for oversight and monitoring
2. Site coordinator
3. Administrator: communications, billing, track accrual, etc.
4. Travel expenses
5. Video conferencing

10-13

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Metrics of Success

1. Number of patients screened; accrual from remote areas
2. Satisfactory performance on QA/QC and audits
3. Training and participation of NH with LI CTSU
4. Ability to enroll patients with molecularly defined subsets
5. Referral of patients for more sophisticated study/treatment to the LI

10-14

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Future Plan

1. Create state-wide Texas Clinical Trials Network **(TCTN)**
2. Link LIs and their networks together
3. Larger and more sophisticated trials
4. Trials of agents emanating from labs in Texas and industry
5. Administrative supplement

10-15

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Proposal 2: Increase Clinical Trial Physicians

1. Physicians interested in clinical investigation is declining
2. Interested oncologists don't have time
3. Hospitals are requiring doctors to see more and more patients (wRVUs)
4. Oncologists will go into private practice where they have higher salaries
5. New oncologists lack opportunity, interest and/or proper training for clinical research
6. Shortage will impair clinical trial and translational patient-oriented research

10-16

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Potential Solutions for CPRIT

CPRIT Clinical Investigator Award

1. Provide training to oncologists early in their career to do clinical research (first 4 years)
2. Partial salary support to provide time for career development and to begin a clinical research career (limit clinical time to .4FTE)
3. Support early career clinical researchers who have made a commitment to focus on patient-oriented research
4. Have a focused recruiting effort for CPRIT scholars interested in clinic investigation*

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Questions?

10-18

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Clinical Trials Advisory Committee
2018 Annual Report

Membership Roster

C. Kent Osborne, M.D., CHAIR
Tina and Dudley Sharp Chair in Oncology
Director, Dan L Duncan Comprehensive Cancer Center
Professor of Medicine and Molecular and Cellular Biology
Baylor College of Medicine

Carlos L. Arteaga, M.D.
Director of the Harold C. Simmons Comprehensive Cancer Center
Associate Dean of Oncology Programs
The University of Texas Southwestern Medical Center

Stephen L. Eck, M.D., Ph.D.
Chief Medical Officer, Immatics US, Inc.

S. Gail Eckhardt, M.D., FASCO
Chair, Department of Oncology
Professor and Associate Dean of Cancer Programs
Director, LIVE**STRONG** Cancer Institutes
Dell Medical School | The University of Texas at Austin

David S. Hong M.D.
Deputy Chair of the Department of Investigational Cancer Therapeutics
Clinical Medical Director of the Clinical Center for Targeted Therapy (CCTT)
Associate Vice President of Clinical Research
University of Texas M.D. Anderson Cancer Center

Ruben A. Mesa, M.D., FACP
Director
Mays Cancer Center (An Affiliation UT Health San Antonio/ MD Anderson Cancer Center)
Mays Family Foundation Distinguished University Presidential Chair
The University of Texas Health Science Center San Antonio
Professor of Medicine

C Patrick Reynolds, M.D., Ph.D.
Director, Cancer Center
Professor of Pediatrics, Internal Medicine, and
Cell Biology & Biochemistry
School of Medicine
Texas Tech University Health Sciences Center

Ray Tabibiazar, M.D.
Chairman, Aravive Biologics,
Managing Director, 526 Ventures, LLC

Proposal to Increase Access to Clinical Trials and Expand Clinical Trial Accrual in Texas
Stage 1: Lead Institution and Network
Stage 2: Network Expansion to Underserved Populations or Geographically Remote Areas

Concept

The past decade has spawned new strategies to treat patients with cancer. Technology has enabled scientists and clinicians to dissect individual patients' cancers down to the very genes that cause them to grow and progress thereby opening new doors to the development of treatment specific for that patient. This Precision Cancer Medicine, as it has been named, requires tests or biomarkers to determine the gene/protein drivers of a given cancer and then new drugs that effectively target and block those drivers. Industry and academic centers have responded by developing new drugs that target these defective pathways resulting in a plethora of new agents that need testing in patients. The sheer number of these new drugs and the requirement that they be tested only in the subset of patients harboring the gene/pathway alteration have made clinical testing of these new agents challenging. No longer do we test a new drug on all patients or all patients with a specific disease like breast or colon cancer. Now these drugs must be tested on a much smaller subset of patients defined by the abnormal driver pathway in their particular tumor. This has resulted in the need to increase the number of patients going on clinical trials (in the past fewer than 5% of all cancer patients annually enter clinical research trials) and the need for more multi-institutional trials.

Another important issue is that many patients who could benefit or desire to participate in a new drug trial don't have access to those trials because: 1) they are from an underserved, underinsured population without access to a cancer center; 2) they don't have close geographic access to an urban center where most of these trials are done; or 3) they can't afford to travel to another destination and stay there for the duration of the clinical trial. This problem often gives rise to a selection bias for the trial in that only insured, white, urban patients are studied in a clinical trial. It is recognized that different ethnic or racial groups may respond differently to a drug and need to be captured in early trials before a new drug enters the marketplace. Thus, solutions to address these issues must consider bringing the trials closer to the patients or providing support to bring the patients to the trial if it can't be done locally. These problems are particularly important in large states like Texas where patients are often hundreds of miles from an academic urban clinical research center offering state-of-the-art clinical trials of new and promising treatments.

There are other barriers to increasing access to clinical trials other than patient financial and geographic concerns and these relate in part to the medical care available in a smaller community.

1. Oncologists don't have the necessary resources or time to establish a clinical trials program that includes an experienced research pharmacist, research nurse, study coordinator, and other staff. These functions are critical for a busy physician to enter patients on a clinical trial.
2. Community physicians may not have the experience or knowledge to carry out clinical trial research if they did not receive training during their oncology fellowships. There

are many regulatory requirements that need to be followed to ensure patient safety and to address other legal issues.
3. Community physicians may not be interested in this aspect of patient care.
4. Certain trials such as sophisticated immune therapy trials with adoptive T cell or CAR T cell therapies, trials involving bone marrow transplantation, or those requiring repeated tumor biopsies to learn if the tumor is responding or resistant to therapy can only be done in experienced centers of excellence.

The **Cancer Prevention and Research Institute of Texas (CPRIT)** is interested in expanding its funding for clinical trials to speed development of new promising drugs and to increase access by cancer patients in Texas to state-of-the-art clinical trials of new treatment strategies. Several strategies are planned:

1. Provide resources to bring patients to a clinical trials center.
2. Expand access to patients in more remote areas by establishing models of experienced lead institutions building a network of smaller hospitals/physician offices that would be provided the resources to establish a clinical trials program locally.

Lead Institution (LI)/Network Model

Stage 1

This Program would be initiated in 2 stages. The first or **Pilot Stage 1** would provide, on a competitive application basis, resources needed to develop a small network, with one or two outlying institutions working with the **LI,** to confirm feasibility of the approach. The **LI** would be provided adequate resources to establish and run the network program and the network facilities would be provided resources required to create a functioning clinical trials infrastructure suitable for certain types of phase 2 and small phase 3 trials. Resources necessary for safe and effective oncology clinical trials include:

Network Affiliates

1. Research pharmacy
2. Research nurse with infusion experience
3. Study coordinator to coordinate data collection and management of patients on the trial.
4. Regulatory coordinator to help with IRB submissions, industry contracts, and other regulatory documentation
5. The nurse and study coordinator would also help the physician with patient education and navigation, informed consent, communication with the **LI**, preparation for QC and audits
6. IRB fees (consider central IRB)
7. Access to the Clinical Trials Monitoring System (OnCore)
8. Support and equipment for processing and storing samples (-80 freezer, centrifuge, supplies)
9. Access to video conferencing

10. Partial funding for a clinical trial leader or champion to support the clinical research effort. This could be linked to a separate RFA for this purpose.
11. Funding for tissue biopsies for research purposes should be included in the particular research trial. This can be a problem for investigator-initiated trials without industry or grant sponsor. This could be sought via a clinical research study grant from CPRIT or other agency.
12. CPRIT funding for OMICs screening for certain trials should be considered.
13. Consent form translation

The network facilities would receive startup funding and then be reimbursed by the **LI** on a per patient basis to encourage accrual. Larger programs may require additional staff depending on patient accrual volume.

Lead Institution

1. Expenses for monitoring and QC/QA visits
2. Additional regulatory staff for oversight, QC/QA, etc.
3. Additional administrative staff to coordinate program, track accrual, research billing, coordinate tumor boards or other CME activities for the network
4. Virtual meeting infrastructure

Metrics of success would include:

1. Trial accrual
2. Number of patients screened for trials
3. Satisfactory performance on QC and audit evaluations
4. Satisfactory staff training and continued participation with the **LI Clinical Trials Support Unit**
5. Ability to enroll patients with molecularly defined subsets
6. Referral of patients with cancers suitable for more sophisticated trials to the **LI** with resources provided by CPRIT via the **LI**

Stage 2

Once **Stage 1** is satisfactorily demonstrated then the **LI** would seek additional funding to expand the network to other facilities using the same design and strategy in **Stage 2**. The focus should be on areas with little access currently to clinical trials. **Stage 2** would focus on enabling the LI Networks to include geographically remote sites or sites with underserved and/or underrepresented patient populations. A critical component of **Stage 2** would be for each LI Network to precisely define and justify the sites they intend to include as well as a tailored implementation plan. A *physician champion* at each of these expansion sites would be a mandated requirement.

Participating institutions would ensure efficiency and speed in the review and activation of trials and use of a common IRB at the lead institution or a central IRB will be required by

institutional master agreements. Institutions with physicians with some research experience and those with other capabilities would be prioritized but other less experience facilities would also be considered based on interest and motivation. Linking the **LIs** and their networks together in one large collaborative consortium would also take place in **Stage 2** after the

Networks are established and functioning. The goal is to form a state-wide **Texas Clinical Trials Network (TCTN)** that functions to streamline hypothesis-driven high-impact trials across the state. This could be accomplished in a manner similar to the NCI's Experimental Therapeutics Clinical Trials Network (ET-CTN) but rather than prioritizing agents developed at CTEP, the intent would be to more rapidly deploy and complete proof-of-concept trials emanating from the LI's own research portfolios as well as agents developed in conjunction with the pharmaceutical industry that serve unmet medical needs of cancer patients in Texas. The funding of this effort could be accomplished as an administrative supplement to Lead Institutions funded through **Stage 2**.

Needed resources are similar to Stage 1 for each of the Network Affiliates. Expanded resources would be needed for the LI to account for the added network sites.

Metrics of success would be similar to **Stage 1.**

Potential CPRIT Expansion of Clinical Scholar Awards

Background: The CPRIT Clinical Trials Advisory Committee met in January 2019 and agreed that expansion of funding opportunities for the recruitment of clinical trial-focused faculty should enhance the current programs. Three distinct areas of focus were discussed:

1. Development of a K12 like program for new Assistant Professors with a focus on clinical investigation
2. Development of a mechanism for salary support for early-mid career investigators to expand clinical trial access/scope/impact across TX
3. Expansion of the current mid-level and established investigator CPRIT recruitment awards to include faculty focused on clinical trials

1. K12 Like program at TX state level

Goals: To expand the impact of therapeutic cancer clinical trials across the state of Texas through support of clinical trial-focused investigators across cancer disciplines [i.e., malignant hematology, solid tumor medical oncology (adult and pediatric), radiation oncology, surgical oncology]. These awards would be used for either recruitment of out-of-state faculty and/or support of junior clinical scholarly faculty already in Texas. CPRIT awards would support salary, protected time, support for additional training (trial design, biostats, clinical research training programs, etc.), clinical trials personnel & infrastructure, patient outreach & education, strategies to increase accrual, and molecular discovery aspects associated with the clinical studies.

Eligibility:

- Clinical scholars/investigators with an active clinical practice in a focused cancer care discipline
- At time of application >/= 40% clinical productivity expectations
- <5 years from completion of clinical training

Funding Parameters:

- Up to 30% salary support
- Up to $50K/year misc. expenses (biostats support, molecular correlatives, meeting travel, education, etc.).
- 3-year award, renewable x 1

Institutional Commitment:

- Commitment to truly protect the protected time supported with commitment to allow the applicant to dedicate >/= 50% of their time on clinical trial training/ design/ etc.
- Adequate support of clinical trial infrastructure for investigator to be successful

Review Criteria:

- Evidence of excellence in clinical training and clinical research
- Evidence of strong mentorship and comprehensive career development plan for the applicant
- Likelihood that receipt of award will expand clinical trial access/accrual to underserved populations, diseases, or geographic regions within Texas

Jonathan MacQuitty
Lightspeed Venture Partners

Since April 2016, Dr. MacQuitty has served as a Venture Partner at Lightspeed Venture Partners, a California-based venture capital firm, helping to lead their investments in life sciences. In July 2018, Lightspeed Ventures closed on an additional $1.8 billion in funding.

Dr. MacQuitty is also currently CEO of D2G Oncology, an oncology biotech start-up recently spun out of Stanford University. Dr. MacQuitty previously served as CEO of Forty Seven, an immuno-oncology company, from its inception in May 2015 until April 2017. In June 2018 Forty Seven completed a $113 million IPO.

From 1999 to 2014, Dr. MacQuitty was a Partner at Abingworth Management, a trans-Atlantic venture capital and investment firm focused on life sciences. Between 1988 until its acquisition 10 years later, he was founding CEO of GenPharm International, a biotech firm focused on discovering and developing novel human type antibodies primarily for cancer. Prior to GenPharm, he was a business development executive at Genencor and Genentech.

Since April 2016, Dr. MacQuitty has been a board director of Teneobio, an oncology antibody platform company. Teneobio recently signed a strategic partnership with Abbvie on a bispecific antibody for multiple myeloma. This included a $90m million upfront payment from Abbvie.

His other board directorships have included Acorda (now NASDAQ), Dicerna (now NASDAQ), Guava (acquired), Labcyte (acquired), Myelos (acquired), Orca, ParAllele BioScience (acquired), Personalis, Quantum Dot (acquired), SFJ Pharma, Sosei (now listed in Tokyo), and Sunesis (now NASDAQ). He has also served on the Board of the Biotechnology Industry Organization (BIO).

Dr. MacQuitty holds an M.A. in Chemistry from Oxford University, a Ph.D. in Chemistry from University of Sussex, and an M.B.A. from Stanford University.

Product Development Research Advisory Committee
Annual Report

Submitted to CPRIT Oversight Committee May 15, 2019

Chair, Jonathan MacQuitty, Ph.D.

The members of the Product Development Advisory Committee (PDAC) appreciate the opportunity to provide the PDAC's annual report and recommendations to the Oversight Committee regarding CPRIT's Product Development Research Program. The PDAC welcomes a continuing dialogue with the Oversight Committee and CPRIT staff to enhance and improve Texas' position as a leader in cancer prevention, cancer research and cancer product development.

Preamble

Texas is recognized for its commitment to research, prevention and treatment of cancer. Along with its world-renowned academic medical centers such as M.D. Anderson Cancer Center, Baylor College of Medicine and UT Southwestern Medical Center, CPRIT has been instrumental in establishing Texas as a top destination for the advancement of innovative, cutting-edge research and the development of diagnostic, therapeutic and medical device products targeting cancer eradication.

CPRIT's Product Development Research Program is actively funding the advancement of disruptive, innovative cancer drug, diagnostic, and tool product development. The Product Development Research Program is attracting some of the best cancer-focused technologies to Texas for company formation and relocation. Companies funded by CPRIT have the potential for a lasting economic and medical benefit to patients through the resulting healthcare innovation and biotechnology ecosystem that otherwise would not exist.

To date, the CPRIT Product Development Research portfolio consists of 40 awarded grants totaling $411.2 million to 34 companies since 2010. The portfolio companies have raised over $1.75 billion in follow-on funding after receiving a CPRIT investment. Additionally, 615 individuals have been hired by portfolio companies as a result of CPRIT funding.

Product Development Advisory Committee Membership

The PDAC is an *ad hoc* advisory committee that offers guidance to the Oversight Committee on issues related to CPRIT's Product Development Research Program. CPRIT's Product Development Research Program reduces the burden of cancer by bringing improved products to market and substantially expanding the Texas life sciences ecosystem focused on cancer applications.

Members of the Oversight Committee and representatives from the life science industry trade association, CPRIT staff, and Texas venture capital companies nominated members of the PDAC.

Listed below are the current PDAC members:

Jonathan MacQuitty, Ph.D., **Chair** *Venture Partner, Lightspeed Venture Partners*	David Lowe, Ph.D.,* **Vice Chair** *Co-Founder, Aeglea Biotherapeutics* *Managing Director, AllosteRx Capital*
David Arthur* *CEO and Director, Salarius Pharmaceuticals*	Bruce Butler, Ph.D. * *Vice President, Research and Technology,* *Director, Office of Technology Management* *UT Health Sciences Center at Houston*
Paul Lammers, M.D.* *CEO, President, and Director Triumvira Immunologics* *Former CEO & President, Mirna Therapeutics*	Gary Latham, Ph.D.* *Sr. V.P., Research and Development, Asuragen*
Kevin LaLande *Managing Director, Santé Ventures*	Andrew Strong, JD* *Partner, Pillsbury Winthrop Shaw Pittman, LLP* *Founding CEO & President, Kalon Biotherapeutics*
Brenton Scott, Ph.D.* *President and COO, Pulmotect*	Greg Stein, M.D.* *CEO, Curtana Pharmaceuticals*
Ilia Tikhomirov* *President and CEO, Formation Biologics*	James Topper, M.D., Ph.D. *Managing General Partner, Frazier Healthcare Partners*
Matt Winkler, Ph.D.* *Founder, Asuragen and Mirna Therapeutics*	

* Past or current CPRIT grantees

Product Development Research Program Priorities

The Oversight Committee's 2019 program priorities for the Product Development Research Program are:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early stage projects when private capital is least available;
- Stimulating commercialization of technologies developed at Texas institutions;
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff, to seed clusters of life science expertise and lead companies at various Texas locations; and
- Providing appropriate return on Texas taxpayer investment.

2019 Product Development Advisory Committee Discussion

The PDAC met on April 11, 2019, to discuss issues related to the Product Development Research Program. In addition to the PDAC membership, CPRIT staff members present included: Wayne Roberts (CEO), Kristen Doyle (GC/DEO), Jim Willson (CSO), Cindy WalkerPeach (CPDO) and Rosemary French (Sr. PD PM). The following CPRIT Product Development Subcommittee Members also attended the meeting: Bill Rice, Craig Rosenfeld and Donald "Dee" Margo.

2019 Product Development Advisory Committee Policy Recommendations

To fulfill CPRIT's statutory mandate and to achieve the Oversight Committee's Program Priorities, the PDAC offers four recommendations:

<u>Recommendation 1: Increase CPRIT outreach both inside and outside Texas</u>
PDAC felt that one way to increase the number of product development grants was to further increase CPRIT's visibility amongst Texas-based technology transfer offices as well as early stage VC's outside of the state of Texas. This would require a two pronged approach:

- Tech transfer offices inside the state need to be made more aware of the available CPRIT Product Development Research grant funding mechanisms. Staff needs to be allowed to allocate time to meeting a wider range of individuals in these offices.
- Out-of-state early stage VCs need to be made more aware of benefits of CPRIT funding to encourage them to consider locating new companies in Texas. Resources need to be made available to staff to travel to major cancer conferences and biotech trade shows to do this.

Recommendation 2: Encourage and support applicants denied awards to re-submit better applications

PDAC felt that applicants can often have interesting applications that may well deserve support but need to be improved before an award can be made. This too would require a multi-pronged approach:

- CPRIT should establish a program whereby applicants who have been denied funding will have access to the "lead reviewer" of their application to better understand how that applicant might improve their application for future submissions and to understand the basis of the critiques that the applicant received from the CPRIT reviewers. This may require additional cost but PDAC felt that this feedback was essential for applicants.
- CPRIT should consider staggering the timing of the Seed Award and the Product Development Award postings so that the Product Development program would be available to applicants on a more timely basis. Running programs every 6 months creates a large time gap for companies whose CPRIT applications are denied.
- CPRIT should have discretion to make "junior awards" for applicants whose applications came closer to approval. These would be in the range of $100,000-500,000 and would enable applicants to go back and complete key experiments, finalize IP, hire grant writers and consultants to improve their applications and development plans.
- CPRIT should establish a list of preferred consultants from Texas and elsewhere who could provide technical help to applicants in areas such as planning for preclinical and clinical development, regulatory affairs, patent matters and grant writing. The consultants would be paid by applicants but having such a list should allow better expertise to be brought to bear.

Recommendation 3: Allow (and encourage) awardees to submit additional applications

PDAC felt that there was no reason to arbitrarily cap awards to specific companies. Companies with one high quality project may well have others. Allowing additional awards increases the chances that the company attracts significant external funding, is able to develop useful products and succeeds in having those products brought to market to the benefit of cancer patients and CPRIT.

Recommendation 4: CPRIT should increase its investment in product development

PDAC unanimously recommended substantially increasing CPRIT's investment in product development, specifically by focusing on providing grant money to support clinical trials. PDAC noted that this recommendation has been made in prior years but that there still remains a significant deficit in product development funding. PDAC members noted that the California Institute of Regenerative Medicine (CIRM), a similar agency to CPRIT, has received criticism for not emphasizing the funding of clinical trials and product development.

Other Discussions

There was a discussion among PDAC as to whether public companies were suitable for CPRIT funding. The potential for increasing the number and quality of product development applications was noted. However such companies already have access to the public financial markets. No unanimous decision was reached. It seemed clear that companies that go public after receiving an award should be allowed to continue to receive CPRIT funding. CPRIT should not be seen in any way as a barrier for Texas companies becoming public companies.

There was discussion about non-profit entities applying for awards. PDAC felt that if non-profit entities can explain how their product could be commercialized and have a clear interest in facilitating this then they should be allowed to apply for CPRIT funding.

PDAC also discussed CPRIT's current Texas-based criteria, which apply to all CPRIT grantees. The PDAC agreed that the current Texas-based criteria requirements are reasonable but that staff should have some flexibility in evaluating these criteria. However PDAC felt that this is an issue where the views of the Oversight Committee and elected officials are paramount. PDAC intends to continue discussion about the criteria at a future meeting to try to ensure that these don't inadvertently limit awards being made to applicants which in fact might be suitable.

APPENDIX

2018 PDAC Recommendations:

Recommendation 1: CPRIT should conduct more outreach to increase the number of high quality applicants.

The number of applications submitted for the past several product development review cycles has remained relatively steady at 20 applications per cycle. Several PDAC members felt that CPRIT is missing opportunities to increase the pipeline of promising company applications, which in turn will boost the number of company awards. CPRIT should raise its profile among the national network of life science venture capitalists and oncology companies. Not only will this help to highlight CPRIT's unique product development research program and the work done by its funded companies in Texas,

but it also provides CPRIT the opportunity to promote its grant program, particularly to companies and investors outside of Texas. In addition to the outreach efforts that CPRIT staff are doing throughout the state, the PDAC believes that it is important for CPRIT staff to attend high profile oncology, life science, and venture capital conferences outside of the state to network with early stage companies and their investors.

Recommendation 2: CPRIT should provide more guidance to potential applicants prior to submitting applications to increase the number of high quality applications.

Unlike a typical angel or venture funding decision process, CPRIT's product development review allows limited interaction between the company and investment decision makers. As a result, missing information or an ambiguity in an application that would be relatively simple to address may cause reviewers to reject the application from consideration. Although CPRIT allows applicants to resubmit their applications in future application cycles, the additional time before the applicant can provide the missing information sought by the reviewers can be substantially disadvantageous to an early stage company. The PDAC recommends that CPRIT enhance support to applicants as they prepare their applications to help ensure high quality submissions. These resources can be webinars with reviewers and CPRIT Product Development Research Program staff that provide insight into the review process and what items constitute an excellent application. CPRIT may also consider working with local business incubators that can provide technical assistance to product development applicants.

Recommendation 3: CPRIT should consider changes to the product development review process to increase the likelihood of success for high quality companies.

All PDAC members are external to the CPRIT product development review process. For those PDAC members who are familiar with recent applications submitted for review, it appears that the Product Development Review Council is becoming less tolerant regarding the degree of risk it will accept in the companies recommended for CPRIT awards. If this is accurate, we believe this is the wrong path for CPRIT to take. Innovations rarely arise from taking the safe course, especially in the initial stages of development. Investing in early stage oncology companies is inherently risky. This was true when CPRIT was created with its mission to expedite innovative treatments for cancer patients and it remains true today.

CPRIT plays a special role by investing in early stage companies before many venture capitalists or other large investors are willing to do so. CPRIT's investments support the preclinical and early clinical trial work that is crucial for attracting additional funding to continue the project. If CPRIT is becoming less tolerant of risk, then a crucial source of investment dries up at a critical stage in company development.

We do not recommend CPRIT lower its standards for the company awards. CPRIT is known in the community as a discerning investor. The significant amount of additional funding raised by companies after receiving their CPRIT awards is testament to CPRIT's rigorous review process. Rather, we recommend that the Oversight Committee endorse its willingness to accept a high degree of risk in the outcome of high-quality projects that are innovative and, if successful, will expedite cancer cures and treatments. CPRIT's willingness to tolerate risk for projects where the impact on cancer treatment is likely to be truly profound should be communicated to potential applicants and, more importantly, to the Product Development Review Council for their consideration during the review process.

In addition to affirming CPRIT's willingness to accept uncertain outcomes, the PDAC also recommends changes to the current review process to increase the number of successful companies. As noted in our second recommendation, there are few opportunities for company applicants to interact with decision makers. As a result, some Product Development Review Council members make their recommendations for grant awards based upon a *de novo* review of the application (6 to 7 months after the application was originally submitted) without having spoken to the company under consideration or having watched their presentation. The PDAC understands that, to some extent, the lack of interaction is due to time constraints and CPRIT's need to maintain a consistent review process for all applicants. At a minimum, the PDAC strongly recommends that a company that has progressed to due diligence has an opportunity to address the full Product Development Review Council and to answer questions and address concerns that arise during the due diligence process. Adding this opportunity during the final phase of the product development review process when only the most likely candidates for awards are still under consideration should not increase significantly the time required for the review. Ensuring that all Product Development Review Council members hear from the company applicant to have their questions addressed may increase the number of companies recommended for awards. Further to this process, the PDAC recommends that applicants be afforded the opportunity to address in their applications the concerns expressed by the Product Development Review Council prior to the Council's final recommendation on the grant award.

Recommendation 4: CPRIT should increase its investment in product development research.

The PDAC discussed how to best utilize remaining CPRIT product development research grant funding, which CPRIT estimates to be approximately $210 million if the current 75/25 split between academic research and product development awards remains in place. The committee unanimously recommended increasing CPRIT's investment in product development, specifically by focusing on providing grant money to support clinical studies and trials.

PDAC members noted that the California Institute of Regenerative Medicine (CIRM), an agency similar to CPRIT in many respects, has received criticism for not emphasizing clinical trials and product development over constructing research buildings and funding basic research. Cures, or at least documented progress towards advancing cures to approval, have been limited in the California experience.

Unlike CIRM, CPRIT has not used its funds to construct buildings. CPRIT has funded more product development than CIRM, as well as a sustained commitment to clinical trial support. However, CPRIT's historical funding weight of 81% towards academic research and recruitment versus 19% for Product Development Research may subject CPRIT to criticism similar to that of CIRM. This will become increasingly important as CPRIT approaches the end of its funding authorization. CPRIT should place significantly greater emphasis on clinical studies and Phase I and II clinical trials when investing CPRIT's remaining grant funds. Clinical trials are the best evidence that the cures many Texans expected when creating CPRIT are under development. Supporting early stage clinical trials is inherently risky and some promising treatments will fail. But not funding clinical trials poses greater risks to the pipeline of potential cancer treatments and cures. CPRIT's investment in a well-designed clinical trial for an innovative treatment that ultimately fails is forgivable; failing to support clinical trials is not.

The PDAC recommends CPRIT emphasize funding clinical projects that will demonstrate human proof of principle in an appropriate period, preferably before the agency's closure, currently set at August 31, 2023. Doing so prioritizes direct patient needs. Currently CPRIT allocates approximately $60 - $70 million per year for product development. This means that CPRIT can awards three to four major Product Development grants annually, typically in the $12 - $20 million range. The PDAC recommends increasing the total amount CPRIT allocates for Product Development by 50% annually ($90 - $100 million). This will increase the number of major awards to five or six grants per year. Doing so increases the probability that the grantees will develop useful cancer products in the period remaining for CPRIT. Continuing at the current level increases the risks that useful cancer products will not be generated before CPRIT ends.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CPRIT
Product Development Advisory Committee (PDAC) Update and Recommendations

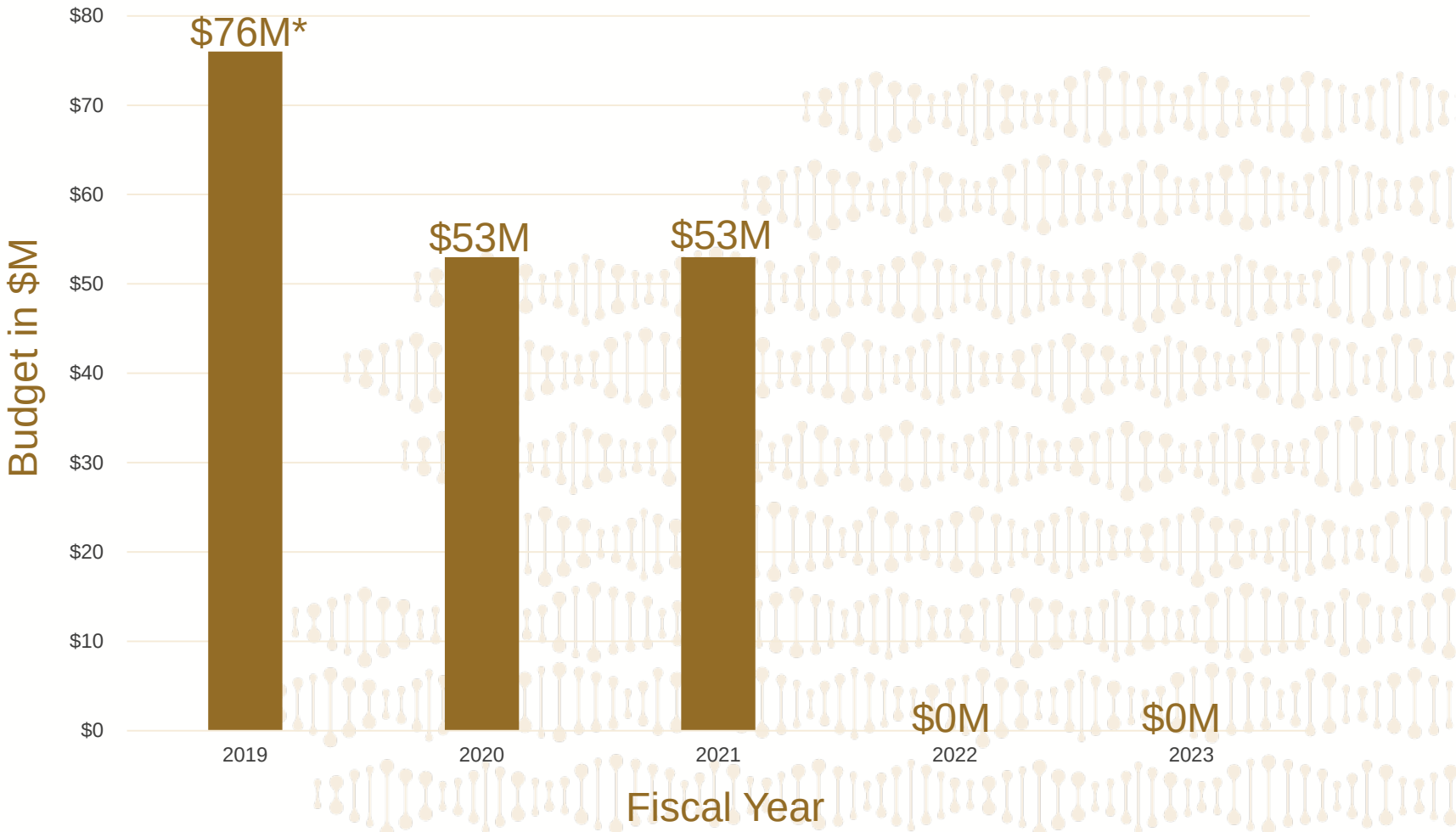
Oversight Committee
May 2019

Jonathan MacQuitty, Ph.D.
Chair, PDAC

Agenda

- CPRIT Product Development Status Update
- Guidance from PDAC to CPRIT
  - Recommendations
  - Other Thoughts

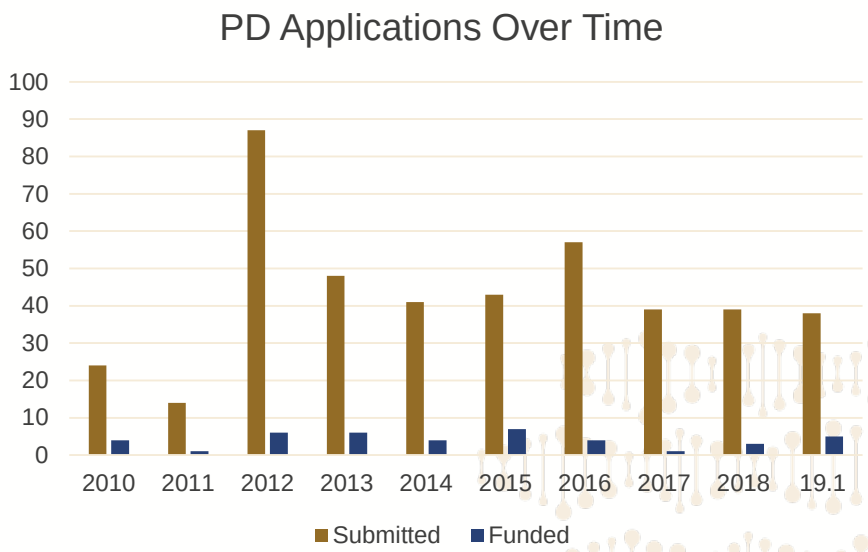
CPRIT PD Status: Ringfenced Funds Available

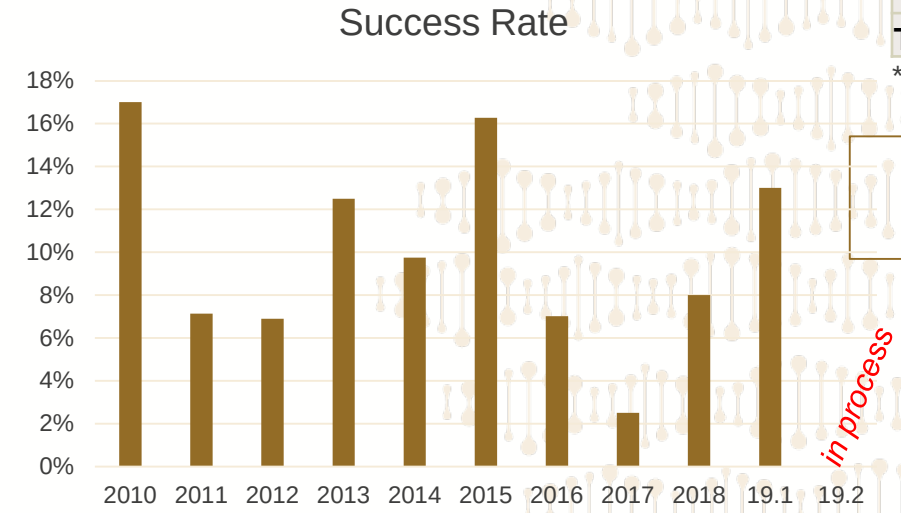


*2019 Budget Status: $30.8M awarded in 19.1 cycle, $45.2M available for 19.2 cycle (in progress)

11-12

Product Development Application History





FY	Submitted	Funded	Success Rate
2010	24	4	17%
2011	14	1	7%
2012	87	6	7%
2013	48	6	13%
2014	41	4	10%
2015	43	7	16%
2016	57	4	7%
2017	39	1	3%
2018	39	3	8%
2019 (Cycle 1)	38	5	13%
2019 (Cycle 2)	27	TBD	TBD
Total	**457**	**41***	
Total 2010-19.1	**430**	**41***	**9.53%**

*CPRIT website : 40 PD awardees. 41 includes one award that was not contracted.

Overall Success Rate: 9.5%
(354 apps, 41 approved awards, 40 contracted)

40 PD awards totaling $411.2M to 34 companies

- 6 companies have received 2 awards
- 16 active awards, 6 in contract negotiation, 18 closed

11-13

Location of PD Awardees

Lubbock

CerRx

Dallas

NEXEON

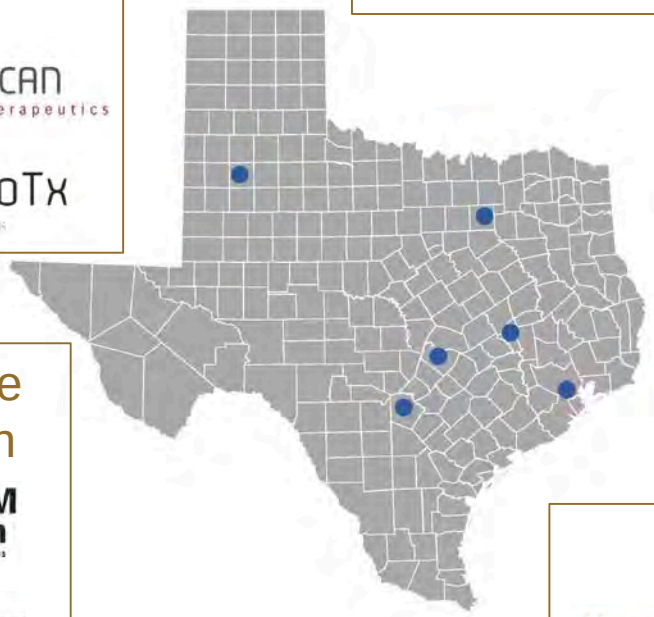
onconano

Peloton Therapeutics

San Antonio

PELICAN Therapeutics

NanoTx



College Station

FUJIFILM Diosynth Biotechnologies

CALIBER biotherapeutics

Houston

aravive BIOLOGICS Outcompeting Cancer™

ALLterum Therapeutics

Bellicum PHARMACEUTICALS

Cell Medica

DNAtrix THERAPEUTICS

ESSA

Hummingbird BIOSCIENCE

immatics

InGeneron

Iterion

kealex THERAPEUTICS

Magnolia Tejas Corporation

MEDICENNA THERAPEUTICS CORP.

PULMOTECT

Salarius PHARMACEUTICALS The Cancer Epigenetics Company

ViraCyte ADVANCING T CELL THERAPY

VISUALASE

Austin

aeglea BIOTHERAPEUTICS

apollo endosurgery

Asuragen

Curtana PHARMACEUTICALS

INSTAPATH

FORBIUS

tem MOLECULAR TEMPLATES

MYRIAD RBM

miRNA THERAPEUTICS

Update on SEED Mechanism

- Released in 19.1 cycle

19.1 Review Cycle Funding Stats by Mechanism

	Apps Received	Funded	Success Rate
TXCO	5	1	20%
RELCO	8	1	12.5%
SEED	25	3	12%
Total	**38**	**5**	**13.2%**

19.2 Review Cycle – In Progress

	Apps Received	Invited to In-Person	Invited to Due Diligence
TXCO	4	3	1
RELCO	9	3	1
SEED	14	5	2
Total	**27**	**11**	**4**

REC 1: Increase CPRIT outreach both inside and outside Texas

- Within Texas: targeting TTOs
- Outside of Texas: targeting early stage VCs
  - Resources need to be made available to staff to travel to major cancer conferences and biotech trade shows to do this.

REC 2: Encourage and support applicants denied awards to re-submit better applications

- Access to lead reviewer
- Staggered timing of Seed & TXCO/RELCO postings
- Possibility of junior awards
- List of consultants: expertise in preclinical and clinical development, regulatory affairs, IP, grant writing

REC 3: Allow (and encourage) awardees to submit additional applications

- No reason to arbitrarily cap awards # of awards to specific companies
- Companies with one high quality project may well have others
- Allowing additional awards increases the chances that the company attracts significant external funding, is able to develop useful products and succeeds in having those products brought to market to the benefit of cancer patients and CPRIT

REC 4: CPRIT should increase its investment in product development

- PDAC unanimously recommended substantially increasing CPRIT's investment in product development, specifically by focusing on providing grant money to support clinical trials.
- California Institute of Regenerative Medicine (CIRM), a similar agency to CPRIT, has received criticism for not emphasizing the funding of clinical trials and product development.

Other Topics of Discussion

- Whether public companies are suitable for CPRIT funding
- Consideration of non-profit applicants
- CPRIT's current TX-based criteria

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CPRIT
Product Development Advisory Committee (PDAC) Update and Recommendations

Oversight Committee
May 2019

Jonathan MacQuitty, Ph.D.
Chair, PDAC

Cancer Prevention & Research Institute of Texas

IA #04-2019 Internal Audit Follow-Up Report over
Post-Award Grant Contracting and Monitoring
Report Date: April 11, 2019
Issued: April 26, 2019

weaver
Assurance • Tax • Advisory

CONTENTS

The Oversight Committee
Cancer Prevention and Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, Texas 78701

This report presents the results of the internal audit follow-up procedures performed over Post Award Grant Contracting and Monitoring for the Cancer Prevention and Research Institute of Texas (CPRIT). The follow-up was performed during the period February 19, 2019, through April 11, 2019 related to the one finding from the Internal Audit Report over Post-Award Grant Contracting and Monitoring dated December 20, 2017.

The objective of these follow up procedures was to validate that adequate corrective action has been taken in order to remediate the issue identified in the audit report.

To accomplish this objective, we conducted interviews with CPRIT personnel responsible for post-award grant contracting and monitoring. We also reviewed documentation and performed specific testing procedures to validate actions taken. Procedures were performed at the CPRIT office.

The following report summarizes the results of our procedures.

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
April 11, 2019

Cancer Prevention and Research Institute of Texas

IA# 04-2019 Internal Audit Follow-Up Report over
Post-Award Grant Contracting and Monitoring
Report Date: April 11, 2019
Issued: April 26, 2019

Background

In fiscal year 2018, an internal audit over Post-Award Grant Contracting and Monitoring at the Cancer Prevention and Research Institute of Texas (CPRIT) was completed. The internal audit report identified one area of improvement.

The 2019 Internal Audit Plan included performing follow-up procedures to validate that CPRIT management has taken steps to address the open internal audit finding.

Follow-Up Objective and Scope

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address the open finding included in the 2018 Internal Audit Report over Post-Award Grant Contracting and Monitoring, and to validate that appropriate corrective action had been taken.

We evaluated the corrective action taken by CPRIT management to address the open internal finding identified.

Executive Summary

The finding from the 2018 Internal Audit Report over Post-Award Grant Contracting and Monitoring was identified and considered to be a non-compliance issue with CPRIT policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover risks to CPRIT. The issue could have significant financial or operational implications.

Through our interviews, review of documentation, observations and testing we determined that the finding was remediated.

A summary of our results is provided in the tables below.

Risk Rating	Total Findings	Remediated	Partially Remediated	Open
High	-	-	-	-
Moderate	1	1	-	-
Low	-	-	-	-
Total	1	1	-	-

Cancer Prevention and Research Institute of Texas

IA# 04-2019 Internal Audit Follow-Up Report over
Post-Award Grant Contracting and Monitoring
Report Date: April 11, 2019
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A summary of our results is provided in the table below. *See the Appendix for an overview of the Assessment and Risk Ratings.*

OVERALL ASSESSMENT	STRONG

SCOPE AREA	RESULT	RATING
Grant Management: Validate that appropriate corrective action has been taken in order to adequately remediate the finding identified in the 2018 Internal Audit Report over Post-Award Grant Contracting and Monitoring.	We identified that remediation efforts were made by CPRIT management for the finding from the 2018 Internal Audit Report over Post-Award Grant Contracting and Monitoring.	STRONG

Conclusion

Based on our evaluation, CPRIT has made satisfactory effort to remediate the finding from the 2018 Internal Audit Report over Post-Award Grant Contracting and Monitoring. Management should continue to focus on maintaining and strengthening internal controls over Grant Contracting and Monitoring processes.

Detailed Follow-Up Results

Cancer Prevention and Research Institute of Texas

IA# 04-2019 Internal Audit Follow-Up Report over
Post-Award Grant Management
Report Date: April 11, 2019
Issued: April 26, 2019

Detailed Follow-Up Results

Our procedures included interviewing key grant management personnel to gain an understanding of the corrective actions taken in order to address the finding identified in the 2018 Internal Audit Report over Post-Award Grant Contracting and Monitoring as well as examining existing documentation and communications and performing testing in order to validate those corrective actions. We evaluated the existing policies, procedures, and processes in their current state.

Objective: Validate Remediation

Validate that adequate corrective action has occurred in order to remediate the issues identified in the 2018 Internal Audit Report over Post-Award Grant Contracting and Monitoring.

Finding 1 – Moderate – Separated Employee User Access: We identified a former CPRIT employee who had access to the CohnReznick portal after they separated employment from the agency on September 30, 2017. The CPRIT employee's access was removed on December 19, 2017.

Recommendation: CPRIT should implement procedures, as part of the employee separations process, to validate that all user accounts have been deactivated, including accounts where third-party vendors administer the user access. The process should include the receipt of positive confirmation from CPRIT IT and third-party vendors that all user IDs have been deactivated, or access has been otherwise removed.

Results: Finding Remediated

We examined users and access permissions to the CohnReznick portal and determined that current users of the portal are active personnel, and permissions to the portal are appropriate based on employee positions and job responsibilities. We also examined the one employee separation that occurred since the completion of the last audit, and identified the separated employee was appropriately removed from the system.

Appendix

Cancer Prevention and Research Institute of Texas

IA# 04-2019 Internal Audit Follow-Up Report over
Post-Award Grant Management
Report Date: April 11, 2019
Issued: April 26, 2019

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

Report Ratings

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and programs
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

Cancer Prevention and Research Institute of Texas

IA# 04-2019 Internal Audit Follow-Up Report over
Post-Award Grant Management
Report Date: April 11, 2019
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Risk Ratings

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

May 2019 Oversight Committee
Internal Audit Status Report
As of April 30, 2019

Weaver and Tidwell, LLP (Weaver) is the outsourced internal auditor of the Cancer Prevention Research Institute of Texas (CPRIT). The Weaver engagement team is led by Alyssa Martin, Partner and Daniel Graves, Partner.

2019 Internal Audit Plan and Schedule

The table below reflects the activity to date Weaver has completed for the 2019 Internal Audit Plan.

NEW INTERNAL AUDITS		
Internal Audit	**Description**	**Timing**
State Reporting	Fieldwork for the State Reporting audit was completed and an exit meeting was held on January 16, 2019. We issued the report on January 25, 2019. The audit resulted in an overall assessment of "Strong" with two Low findings: • Tracking and communicating report deadlines to CPRIT personnel with responsibility for report completion • Documenting procedures over the expected processes for managing and monitoring state reporting requirements Follow-up procedures on the remediation of the findings will be included in the proposed audit plan for fiscal year 2020.	Complete
Budget and Planning	Fieldwork for the Budget and Planning audit was completed and an exit meeting was held on January 16, 2019. We issued the report on January 25, 2019. The audit resulted in an overall assessment of "Strong" with no findings.	Complete

FOLLOW-UP PROCEDURES		
Follow-Up	**Description**	**Timing**
SAO Performance Measures Follow-Up • 3 Findings	Fieldwork for these follow-up procedures was completed on December 5, 2018. The report was issued December 12, 2018. All three findings from the prior audit were remediated.	Compete

Post-Award Grant Monitoring Follow-up • 1 Moderate Finding	Fieldwork for these follow-up procedures was completed on April 11, 2019. The report was issued April 26, 2019. The open finding from the prior audit was remediated.	Complete
Procurement and P-Cards Follow-up • 1 Moderate Finding	Fieldwork for these follow-up procedures was initiated in February 2019. Completion of procedures was postponed due to the recent implementation of the new State travel booking system. Additional procedures to validate the current travel reimbursement process will be completed in June 2019.	June 10, 2019 – June 21, 2019
Information Security Follow-Up	Internal Audit will perform follow-up procedures on the open findings from the 2016 Internal Audit to ensure corrective action has been taken.	June 10, 2019 – June 21, 2019
Communications Follow-Up • 1 High Finding • 4 Moderate Findings	Internal Audit will perform follow-up procedures on the 5 open findings from the 2018 Internal Audit to ensure corrective action has been taken.	June 10, 2019 – June 21, 2019

We have prepared a summary schedule of audits, their status and a summary of the findings by risk rating. The schedule maps out the internal audit and follow-up procedures performed, by year, the report date, report rating, and the findings by risk rating. The summary schedule is attached.

Alyssa G. Martin, CPA, MBA, Internal Auditor
Executive Partner
Weaver and Tidwell L.L.P

					-	8	3	34	-	-	-	18	1	
nal Audit	2016	Complete	May 13, 2016	Satisfactory	-	3	2	5	-	-	-	-	-	
	2016	Complete	July 8, 2016	Strong	-	-	2	2	-	-	-	-	-	
	2016	Complete	August 3, 2016	Unsatisfactory	4	6	1	11	-	-	-	-	4	
	2016	Complete	August 12, 2016	Strong	-	1	-	1	-	-	-	-	-	
	2016	Complete	June 9, 2016	Strong	-	8	1	9	-	8	1	9	-	
	2016	Complete	N/A	N/A	-	1	1	2	-	1	1	2	-	
					4	**19**	**7**	**30**	**-**	**9**	**2**	**11**	**4**	
	2017	Complete	March 10, 2017	Strong	-	2	-	2	-	-	-	-	-	
	2017	Complete	April 17, 2017	Strong	-	1	-	1	-	-	-	-	-	
	2017	Complete	May 30, 2017	Satisfactory	1	2	-	3	-	-	-	-	1	
	2017	Complete	August 4, 2017	Satisfactory	-	7	2	9	-	-	-	-	-	
	2017	Complete	May 30, 2017	Unsatisfactory	4	6	1	11	1	2	1	4	3	
Follow-Up	2017	Complete	July 13, 2017	Strong	-	3	2	5	-	3	2	5	-	
	2017	Complete	July 8, 2017	Strong	-	-	2	2	-	-	2	2	-	
	2017	Complete	July 13, 2017	Strong	-	1	-	1	-	1	-	1	-	
					5	**22**	**7**	**34**	**1**	**6**	**5**	**12**	**4**	
dit	2018	Complete	February 1, 2018	Strong	-	1	-	1	-	-	-	-	-	
	2018	Complete	April 30, 2018	Satisfactory	1	4	-	5	-	-	-	-	1	
	2018	Complete	July 17, 2018	Strong	4	6	1	11	4	5		9	-	
	2018	Complete	January 19, 2018	Strong	-	2	-	2	-	2	-	2	-	
v-Up	2018	Complete	January 19, 2018	Strong	-	1	-	1	-	1	-	1	-	
ow-Up	2018	Complete	April 24, 2018	Strong	1	2	-	3	1	2	-	3	-	
)	2018	Complete	April 30, 2018	Strong	-	7	2	9	-	6	2	8	-	
					6	**23**	**3**	**32**	**5**	**16**	**2**	**23**	**1**	
	2019	December 2018	January 25, 2019	Strong	-	-	2	2	-	-	-	-	-	
	2019	December 2018	January 25, 2019	Strong	-	-	-	-	-	-	-	-	-	
-up	2019	November 2018	December 6, 2018	Strong	-	-	3	3	-	-	3	3	-	
	2019	June 2019	TBD	TBD	4	6	1	11	4	5	-	9	-	
	2019	June 2019	TBD	TBD	1	4	-	5	-	-	-	-	1	
v-U	2019	February 2019	April 11, 2019	Strong	-	1	-	1	-	1	-	1	-	
)	2019	June 2019	TBD	TBD	-	7	2	9	-	6	2	8	-	
					5	**18**	**8**	**31**	**4**	**12**	**5**	**21**	**1**	

12-13

FISCAL YEAR 2019 SUMMARY

	Fiscal				Findings				Closed Findings				Total

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN PAULING DOYLE, GENERAL COUNSEL CAMERON L. ECKEL, STAFF ATTORNEY
SUBJECT:	CHAPTER 703 RULE CHANGES PROPOSED FOR FINAL ADOPTION
DATE:	MAY 2, 2019

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee adopt the proposed administrative rule changes to Chapter 703 as originally considered at the February meeting. Once the Oversight Committee approves the final order adopting the rule changes, CPRIT will submit the amendments to the Secretary of State and the changes will be effective 20 days later.

Discussion

State law requires an agency to set policy using a rulemaking process, which includes an opportunity for public comment on proposed rules and rule changes before the agency formally adopts the policy.

The Oversight Committee approved publication of the following proposed rule amendments to §§ 703.6, 703.13, and 703.26 at the February meeting.

- The change to § 703.6(e) clarifies that the Product Development Review Council (PDRC) may conduct business operations and management due diligence for product development applications. Grant applications for product development awards go through the additional step of business and intellectual property due diligence. CPRIT contracts with an outside vendor to perform the business diligence. The rule change permits CPRIT to use one or more PDRC members to perform due diligence due to logistical needs or to address special areas of expertise.

- The amendment to § 703.13(f) clarifies the areas that grantees should cover if they are submitting a program specific audit to CPRIT. Grantees who expend $750,000 or more in state funds are required to submit an independent audit, a program

specific audit, or an agreed upon procedures engagement. The change to § 703.13 elaborates on what the information included in the program specific audit. CPRIT's *Policies and Procedure Guide* will also be updated to provide explanation of program specific audit requirements.

- The change to § 703.26(e)(4)(B) clarifies the unallowable grantee expenses includes fundraising and tips or gratuities. This change ensures that CPRIT's administrative rules are consistent with current processes for disallowing expenses and the Comptroller's *Uniform Grant Management Standards*

The Board Governance Subcommittee met on May 2nd to review the final order with CPRIT's General Counsel. The Subcommittee recommends the Oversight Committee approve the final order adopting the proposed rule changes.

Next Steps

After the Oversight Committee adopts the proposed rule changes, CPRIT will submit the final order to the Secretary of State. The rule changes become effective 20 days after the date CPRIT files the order with the Secretary of State.

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to 25 Tex. Admin. Code §§703.6, 703.13, and 703.26 without changes to the proposed amendments as published in the March 29, 2019, issue of the Texas Register (44 TexReg 1561), therefore, the rules will not be republished. The amendments clarify product development grant application review, program specific audit methodology for grantees, and unallowable costs.

Reasoned Justification

The proposed amendment to §703.6(e)(4)(B) clarifies that the Product Development Review Council (PDRC) may perform business operations and management due diligence for product development application, which go through both business and intellectual property due diligence. The proposed change to §703.13(f) clarifies what areas need to be included in a program specific audit provided by a grantee. Grant recipients who expend $750,000 or more in state funds are required to submit a single independent audit, program specific audit, or agreed upon procedures engagement. The proposed amendment to §703.26(e) adds fundraising and tips or gratuities to the list of items that grant recipients will not be reimbursed with grant funds.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding the proposed amendments to §§ 703.6, 703.13, and 703.26.

The rule changes are adopted under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that Kristen Pauling Doyle, General Counsel, reviewed the adoption of the rules and found it to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on May 16, 2019.

<rule>

§703.6.Grant Review Process.

(a) For all Grant Applications that are not administratively withdrawn by the Institute for noncompliance or otherwise withdrawn by the Grant Applicant, the Institute shall use a two-stage Peer Review process.

(1) The Peer Review process, as described herein, is used to identify and recommend meritorious Cancer Research projects, including those projects with Cancer Research Product Development prospects, and evidence-based Cancer Prevention and Control projects for Grant Award consideration by the Program Integration Committee and the Oversight Committee.

(2) Peer Review will be conducted pursuant to the requirements set forth in Chapter 702 of this title (relating to Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute) and Chapter 102, Texas Health and Safety Code.

(b) The two stages of the Peer Review Process used by the Institute are:

(1) Evaluation of Grant Applications by Peer Review Panels; and

(2) Prioritization of Grant Applications by the Prevention Review Council, the Product Development Review Council, or the Scientific Review Council, as may be appropriate for the Grant Program.

(c) Except as described in subsection (e) of this section, the Peer Review Panel evaluation process encompasses the following actions, which will be consistently applied:

(1) The Institute distributes all Grant Applications submitted for a particular Grant Mechanism to one or more Peer Review Panels.

(2) The Peer Review Panel chairperson assigns each Grant Application to no less than two panel members that serve as the Primary Reviewers for the Grant Application. Assignments are made based upon the expertise and background of the Primary Reviewer in relation to the Grant Application.

(3) The Primary Reviewer is responsible for individually evaluating all components of the Grant Application, critiquing the merits according to explicit criteria published in the Request for Applications, and providing an individual Overall Evaluation Score that conveys the Primary Reviewer's general impression of the Grant Application's merit. The Primary Reviewers' individual Overall Evaluation Scores are averaged together to produce a single initial Overall Evaluation Score for the Grant Application.

(4) The Peer Review Panel meets to discuss the Grant Applications assigned to the Peer Review Panel. If there is insufficient time to discuss all Grant Applications, the Peer Review Panel chairperson determines the Grant Applications to be discussed by the panel. The chairperson's decision is based largely on the Grant Application's initial Overall Evaluation Score; however a Peer Review Panel member may request that a Grant Application be discussed by the Peer Review Panel.

(A) If a Grant Application is not discussed by the Peer Review Panel, then the initial Overall Evaluation Score serves as the final Overall Evaluation Score for the Grant Application. The Grant Application is not considered further during the Grant Review Cycle.

(B) If a Grant Application is discussed by the Peer Review Panel, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.

(i) The panel chairperson participates in the discussion but does not score Grant Applications.

(ii) A Primary Reviewer has the option to revise his or her score for the Grant Application after panel discussion or to keep the same score submitted during the initial review.

(C) If the Peer Review Panel recommends changes to the Grant Award funds amount requested by the Grant Applicant or to the goals and objectives or timeline for the proposed project, then the recommended changes and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(5) At the conclusion of the Peer Review Panel evaluation, the Peer Review Panel chairperson submits to the appropriate Review Council a list of Grant Applications discussed by the panel ranked in order by the final Overall Evaluation Score. Any changes to the Grant Award funding amount or to the project goals and objectives or timeline recommended by the Peer Review Panel shall be provided to the Review Council at that time.

(d) The Review Council's prioritization process for Grant Award recommendations encompasses the following actions, which will be consistently applied:

(1) The Review Council prioritizes the Grant Application recommendations across all the Peer Review Panels by assigning a Numerical Ranking Score to each Grant Application that was discussed by a Peer Review Panel. The Numerical Ranking Score is substantially based on the final Overall Evaluation Score submitted by the Peer Review Panel, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications.

(2) The Review Council's recommendations are submitted simultaneously to the presiding officers of the Program Integration Committee and Oversight Committee. The recommendations, listed in order by Numerical Ranking Score shall include:

(A) An explanation describing how the Grant Application meets the Review Council's standards for Grant Award funding;

(B) The final Overall Evaluation Score assigned to the Grant Application by the Peer Review Panel, including an explanation for ranking one or more Grant Applications ahead of another Grant Application with a more favorable final Overall Evaluation Score; and

(C) The specified amount of the Grant Award funding for each Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the goals and objectives or timeline.

(3) A Grant Award recommendation is not final until the Review Council formally submits the recommendation to the presiding officers of the Program Integration Committee and the Oversight Committee. The Program Integration Committee, and, if appropriate, the Oversight

Committee must make a final decision on the Grant Award recommendation in the same state fiscal year that the Review Council submits its final recommendation.

(e) Circumstances relevant to a particular Grant Mechanism or to a Grant Review Cycle may justify changes to the dual-stage Peer Review process described in subsections (c) and (d) of this section. Peer Review process changes the Institute may implement are described in this subsection. The list is not intended to be exhaustive. Any material changes to the Peer Review process, including those listed in this subsection, shall be described in the Request for Applications or communicated to all Grant Applicants.

(1) The Institute may use a preliminary evaluation process if the volume of Grant Applications submitted pursuant to a specific Request for Applications is such that timely review may be impeded. The preliminary evaluation will be conducted after Grant Applications are assigned to Peer Review Panels but prior to the initial review described in subsection (c) of this section. The preliminary evaluation encompasses the following actions:

(A) The criteria and the specific Grant Application components used for the preliminary evaluation shall be stated in the Request for Applications;

(B) No less than two Peer Review Panel members are assigned to conduct the preliminary evaluation for a Grant Application and provide a preliminary score that conveys the general impression of the Grant Application's merit pursuant to the specified criteria; and

(C) The Peer Review Panel chairperson is responsible for determining the Grant Applications that move forward to initial review as described in subsection (c) of this section. The decision will be based upon preliminary evaluation scores. A Grant Application that does not move forward to initial review will not be considered further and the average of the preliminary evaluation scores received becomes the final Overall Evaluation Score for the Grant Application.

(2) The Institute shall assign all Grant Applications submitted for recruitment of researchers and clinicians to the Scientific Review Council.

(A) The Scientific Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the proposed recruitment.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one recruitment Grant Application is reviewed by the Scientific Review Council during the Grant Review Cycle, then the Scientific Review Council shall assign a Numerical Ranking Score to each Grant Application to convey its prioritization ranking.

(D) If the Scientific Review Council recommends a change to the Grant Award funds requested by the Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Scientific Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this section.

(3) The Institute may assign continuation Grant Applications to the appropriate Review Council.

(A) The Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the progress and continued funding.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one continuation Grant Application is reviewed by the Review Council during the Grant Review Cycle, then the Review Council shall assign a Numerical Ranking Score to each continuation Grant Application to convey its prioritization ranking.

(D) If the Review Council recommends a change to the Grant Award funds or to the scope of work or timeline requested by the continuation Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this section.

(4) The Institute's Peer Review process described in subsections (c) and (d) of this section may include the following additional process steps for Product Development of Cancer Research Grant Applications:

(A) A Grant Applicant may be invited to deliver an in-person presentation to the Peer Review Panel. The Product Development Review Council chairperson is responsible for deciding which Grant Applicants will make in-person presentations. The decision is based upon the initial Overall Evaluation Scores of the primary reviewers following a discussion with Peer Review Panel members, as well as explicit criteria published in the Request for Applications.

(i) Peer Review Panel members may submit questions to be addressed by the Grant Applicant at the in-person presentation.

(ii) A Grant Application that is not presented in-person will not be considered further. The average of the primary reviewers' initial Overall Evaluation Scores will be the final Overall Evaluation Score for the Grant Application.

(iii) Following the in-person presentation, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.

(B) A Grant Application may undergo business operations and management due diligence review and an intellectual property review. The Peer Review Panel submits a list of applications recommended for due diligence review to the Product Development Review Council. The Product Development Review Council decides which Grant Applications submitted by the Peer Review Panel will undergo business operations and management due diligence and intellectual property review. The decision is based upon the Grant Application's final Overall Evaluation Score, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications. A Grant Application that is not recommended for due diligence and intellectual property review will not be considered further.

(i) Business operations and management due diligence may be conducted by an outside vendor, contracted by the Institute or by members of the Product Development Review Council.

(ii) It will be at the Institute's discretion as to who to use to perform business operations and management due diligence; factors may include volume of work and expertise required.

(C) After receipt of the business operations and management due diligence and intellectual property reviews for a Grant Application, the Product Development Review Council and the Primary Reviewers meet to determine whether to recommend the Grant Application for a Grant Award based upon the information set forth in the due diligence and intellectual property reviews. The Product Development Review Council may recommend changes to the Grant Award budget and goals and objectives or timeline

(D) The Product Development Review Council assigns a Numerical Ranking Score to each Grant Application recommended for a Grant Award.

(f) Institute Employees and Oversight Committee members may attend Peer Review Panel and Review Council meetings. If an Institute Employee or an Oversight Committee member attends a Peer Review Panel meeting or a Review Council meeting, the attendance shall be recorded and the Institute Employee or Oversight Committee member shall certify in writing compliance with the Institute's Conflict of Interest rules. The Institute Employee's and Oversight Committee member's attendance at the Peer Review Panel meeting or Review Council meeting is subject to the following restrictions:

(1) Unless waived pursuant to the process described in Chapter 702, §702.17 of this title (relating to Exceptional Circumstances Requiring Participation), Institute Employees and Oversight Committee members shall not be present for any discussion, vote, or other action taken related to a Grant Applicant if the Institute Employee or Oversight Committee member has a Conflict of Interest with that Grant Applicant; and

(2) The Institute Employee or Oversight Committee member shall not participate in a discussion of the merits, vote, or other action taken related to a Grant Application, except to answer technical or administrative questions unrelated to the merits of the Grant Application and to provide input on the Institute's Grant Review Process.

(g) The Institute's Chief Compliance Officer shall observe meetings of the Peer Review Panel and Review Council where Grant Applications are discussed.

(1) The Chief Compliance Officer shall document that the Institute's Grant Review Process is consistently followed, including observance of the Institute's established Conflict of Interest rules and that participation by Institute employees, if any, is limited to providing input on the Institute's Grant Review Process and responding to committee questions unrelated to the merits of the Grant Application. Institute Program staff shall not participate in a discussion of the merits, vote, or any other action taken related to a Grant Application.

(2) The Chief Compliance Officer shall report to the Oversight Committee prior to a vote on the award recommendations specifying issues, if any, that are inconsistent with the Institute's established Grant Review Process.

(3) Nothing herein shall prevent the Institute from contracting with an independent third party to serve as a neutral observer of meetings of the Peer Review Panel and/or the Review Council where Grant Applications are discussed and to assume the reporting responsibilities of the Chief Compliance Officer described in this subsection. In the event that the independent third party observes the meeting of the Peer Review Panel and/or the Review Council, then the independent third party reviewer shall issue a report to the Chief Compliance Officer specifying issues, if any, that are inconsistent with the Institute's established Grant Review Process.

(h) Excepting a finding of an undisclosed Conflict of Interest as set forth in §703.9 of this chapter (relating to Limitation on Review of Grant Process), the Review Council's decision to not include a Grant Application on the prioritized list of Grant Applications submitted to the Program Integration Committee and the Oversight Committee is final. A Grant Application not included on the prioritized list created by the Review Council shall not be considered further during the Grant Review Cycle.

(i) At the time that the Peer Review Panel or the Review Council concludes its tasks for the Grant Review Cycle, each member shall certify in writing that the member complied with the Institute's Conflict of Interest rules. An Institute Employee or an Oversight Committee member attending one or more Peer Review Panel meetings during the Grant Review Cycle shall certify compliance with the Institute's Conflict of Interest rules.

(j) The Institute shall retain a review record for a Grant Application submitted to the Institute, even if the Grant Application did not receive a Grant Award. Such records will be retained by the Institute's electronic Grant Management System. The records retained by the Institute must include the following information:

(1) The final Overall Evaluation Score and Numerical Ranking Score, if applicable, assigned to the Grant Application;

(2) The specified amount of the Grant Award funding for the Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the goals and objectives or timeline;

(3) The Scientific Research and Prevention Programs Committee that reviewed the Grant Application;

(4) Conflicts of Interest, if any, with the Grant Application identified by a member of the Scientific Research and Prevention Programs Committee, the Review Council, the Program Integration Committee, or the Oversight Committee; and

(5) Documentation of steps taken to recuse any member or members from the Grant Review Process because of disclosed Conflicts of Interest.

(k) For purposes of this rule, a Peer Review Panel chairperson or a Review Council chairperson that is unable to carry out his or her assigned duties due to a Conflict of Interest with regard to one or more Grant Applications or for any other reason may designate a co-chairperson from among the appointed Scientific Research and Prevention Programs committee members to fulfill the chairperson role. Such designation shall be recorded in writing and include the specific time and extent of the designation

§703.13.Audits and Investigations.

(a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(1) A Grant Recipient shall maintain its records pertaining to the specific Grant Contract for a period of three years following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(2) The Grant Recipient may maintain its records in either electronic or paper format.

(b) Notwithstanding the foregoing, the Grant Recipient shall submit a single audit determination form no later than 60 days following the close of the Grant Recipient's fiscal year. The Grant Recipient shall report whether the Grant Recipient has expended $750,000 or more in state awards during the Grant Recipient's fiscal year. If the Grant Recipient has expended $750,000 or more in state awards in its fiscal year, the Grant Recipient shall obtain either an annual single independent audit, a program specific independent audit, or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants and pursuant to guidance provided in subsection (e) of this section.

(1) The audited time period is the Grant Recipient's fiscal year.

(2) The audit must be submitted to the Institute within thirty (30) days of receipt by the Grant Recipient but no later than nine (9) months following the close of the Grant Recipient's fiscal year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.

(A) The Grant Recipient may seek additional time to submit the required audit and corrective action plan by providing a written explanation for its failure to timely comply and providing an expected time for the submission.

(B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan. For purposes of this rule, the "due date of the required audit" is no later than nine (9) months following the close of the Grant Recipient's fiscal year.

(C) Approval of the Grant Recipient's request for additional time is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(c) No reimbursements or advances of Grant Award funds shall be made to the Grant Recipient if the Grant Recipient is delinquent in filing the required audit and corrective action plan. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may receive reimbursements or advances of Grant Award funds during the pendency of the delinquency unless the Institute's approval declines to permit reimbursements or advances of Grant Award funds until the delinquency is addressed.

(d) A Grant Recipient that is delinquent in submitting to the Institute the audit and corrective action plan required by this section is not eligible to be awarded a new Grant Award or a continuation Grant Award until the required audit and corrective action plan are submitted. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may remain eligible to be awarded a new Grant Award or a continuation Grant Award unless the Institute's approval declines to continue eligibility during the pendency of the delinquency.

(e) For purposes of this rule, an agreed upon procedures engagement is one in which an independent certified public accountant is hired by the Grant Recipient to issue a report of findings based on specific procedures to be performed on a subject matter.

(1) The option to perform an agreed upon procedures engagement is intended for a non-profit or for-profit Grant Recipient that is not subject to Generally Accepted Government Audit Standards (also known as the Yellow Book) published by the U.S. Government Accountability Office.

(2) The agreed upon procedures engagement will be conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants.

(3) The certified public accountant is to perform procedures prescribed by the Institute and to report his or her findings attesting to whether the Grant Recipient records is in agreement with stated criteria.

(4) The agreed upon procedures apply to all current year expenditures for Grant Awards received by the Grant Recipient. Nothing herein prohibits the use of a statistical sample consistent with the American Institute of Certified Public Accountants' guidance regarding government auditing standards and 2 CFR Part 200, Subpart F, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

(5) At a minimum, the agreed upon procedures report should address:

(A) Processes and controls;

(B) The Grant Contract;

(C) Indirect Costs;

(D) Matching Funds, if appropriate;

(E) Grant Award expenditures (payroll and non-payroll related transactions);

(F) Equipment;

(G) Revenue Sharing and Program Income;

(H) Reporting; and

(I) Grant Award closeout.

(6) The certified public accountant should consider the specific Grant Mechanism and update or modify the procedures accordingly to meet the requirements of each Grant Award and the Grant Contract reviewed.

(f) For purposes of this rule, a program specific audit should address:

(1) sample of awards;

(2) reporting;

(3) Indirect costs;

(4) Matching funds, if appropriate;

(5) expenditures;

(6) Expenditure Reporting;

(7) Personnel Level of Effort Reporting;

(8) Grant Closeout;

(9) Performance Measures;

(10) Publications and Acknowledgements;

(11) Title to equipment;

(12) Contract certifications;

(13) Changes in Principal Investigator or Program Director;

(14) Intellectual Property and revenue sharing;

(15) early termination and event of default; and

(16) any other issue identified by the Institute, the Grant Recipient, or the person performing the program specific audit.

(g) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§703.26.Allowable Costs.

(a) A cost is an Allowable Cost and may be charged to the Grant Award if it is reasonable, allocable, and adequately documented.

(1) A cost is reasonable if the cost does not exceed that which would be incurred by a prudent individual or organization under the circumstances prevailing at the time the decision was made

to incur the cost; and is necessary for the performance of the Grant Award defined in the Scope of Work in the Grant Contract.

(2) A cost is allocable if the cost:

(A) Benefits the Grant Award either directly or indirectly, subject to Indirect Cost limits stated in the Grant Contract;

(B) Is assigned the Grant Award in accordance with the relative benefit received;

(C) Is allowed or not prohibited by state laws, administrative rules, contractual terms, or applicable regulations;

(D) Is not included as a cost or used to meet Matching Fund requirements for any other Grant Award in either the current or a prior period; and

(E) Conforms to any limitations or exclusions set forth in the applicable cost principles, administrative rules, state laws, and terms of the Grant Contract.

(3) A cost is adequately documented if the cost is supported by the organization's accounting records and documented consistent with §703.24 of this title (relating to Financial Status Reports).

(b) Grant Award funds must be used for Allowable Costs as provided by the terms of the Grant Contract, Chapter 102, Texas Health and Safety Code, the Institute's administrative rules, and the Uniform Grant Management Standards (UGMS) adopted by the Comptroller's Office. If guidance from the Uniform Grant Management Standards on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, Texas Health and Safety Code or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.

(c) An otherwise Allowable Cost will not be eligible for reimbursement if the Grant Recipient incurred the expense outside of the Grant Contract term, unless the Grant Recipient has received written approval from Institute's Chief Executive Officer to receive reimbursement for expenses incurred prior to the effective date of the Grant Contract.

(d) An otherwise Allowable Cost will not be eligible for reimbursement if the benefit from the cost of goods or services charged to the Grant Award is not realized within the applicable term of the Grant Award. The Grant Award should not be charged for the cost of goods or services that benefit another Grant Award or benefit a period prior to the Grant Contract effective date or after the termination of the Grant Contract.

(e) Grant Award funds shall not be used to reimburse unallowable expenses, including, but not limited to:

(1) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.

(2) Contributions to a contingency reserve or any similar provision for unforeseen events.

(3) Contributions and donations made to any individual or organization.

(4) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.

(5) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.

(6) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.

(7) An honorary gift or a gratuitous payment.

(8) Interest and other financial costs related to borrowing and the cost of financing.

(9) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.

(10) Liability insurance coverage.

(11) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.

(12) Professional association fees or dues for the Grant Recipient or an individual.

(13) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.

(14) Fees for visa services.

(15) Payments to a subcontractor if the subcontractor working on a Grant Award project employs an individual who is a Relative of the Principal Investigator, Program Director, Company Representative, Authorized Signing Official, or any person designated as Key Personnel for the same Grant Award project (collectively referred to as "affected Relative"), and:

(A) the Grant Recipient will be paying the subcontractor with Grant Award funds for any portion of the affected Relative's salary; or

(B) the Relative submits payment requests on behalf of the subcontractor to the Grant Recipient for payment with Grant Award funds.

(C) For exceptional circumstances, the Institute's Chief Executive Office may grant an exception to allow payment of Grant Award funds if the Grant Recipient notifies the Institute prior to finalizing the subcontract. The Chief Executive Officer must notify the Oversight Committee in writing of the decision to allow reimbursement for the otherwise unallowable expense.

(D) Nothing herein is intended to supersede a Grant Recipient's internal policies, to the extent that such policies are stricter.

(16) Fundraising.

(17) Tips or gratuities.

(f) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Allowable Cost.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: KRISTEN PAULING DOYLE, GENERAL COUNSEL
CAMERON L. ECKEL, STAFF ATTORNEY

SUBJECT: CHAPTER 703 PROPOSED RULE CHANGES

DATE: MAY 2, 2019

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee approve the proposed administrative rule changes for publication in the *Texas Register* for public comment. The proposed changes affect Texas Administrative Code Chapter 703.

Discussion

CPRIT's administrative rules set policy guiding CPRIT's grant review and grant contracting processes as well as administering other requirements of Texas Health and Safety Code Chapter 102. State law requires agencies to use a rulemaking process, which includes an opportunity for the public to comment on proposed rules and rule changes before the agency adopts the final policy.

The Board Governance subcommittee met on May 2nd to discuss the proposed rule changes to §§ 703.3, 703.10, 703.14, and 703.25 with legal staff.

- The proposed amendment to § 703.3(b) clarifies how CPRIT will make any modifications to a published Request for Applications (RFA) available to the public. The proposed amendment makes it clear that the modified RFA (with a revision history in the document) will be posted on CPRIT's public website.

- The proposed rule amendment to § 703.10(c)(22) requires that grantees request approval of temporary leaves of absence of a Principal Investigator, Program Director, or Company Representative. Grantees are required to notify the agency and seek approval of changes in effort of senior members or key personnel of a grant, but the current rule is silent regarding a leave of absence. This proposed amendment clarifies that the grantee must seek CPRIT approval for a proposed leave of absence. This is similar to NIH and NSF policies.

- The proposed change to § 703.14(c)(3) eliminates automatic approval for a grantee's first no cost extension. Under the current rule, CPRIT automatically approves a grantee's first no cost extension if the proposed contract extension is six months or less and the grantee is in good fiscal and programmatic standings. However, there may be extenuating circumstances weighing against extending the contract term, even for an initial request.

- The proposed amendment to § 703.25(e) clarifies when a grantee may make a budget transfer or change without prior approval from CPRIT. The amendment provides for automatic approval when the total dollar amount of the proposed change within the budget category is 10% or less of the total budget for the grant year. While the transfer or change may be made without prior approval, the proposed amendment provides that CPRIT may review the frequency of budget change requests for a grant project and reverse approval of one or more budget changes or transfers, if necessary.

The subcommittee voted to recommend approval and publication of the proposed rule changes to the Oversight Committee.

Next Steps

CPRIT will publish the proposed rule changes in the *Texas Register*. The publication date begins the 30-day period soliciting public comment. CPRIT will post the proposed rule on CPRIT's website and announce the opportunity for public comment via the CPRIT electronic list serve. CPRIT legal staff will summarize all public comments for the Oversight Committee's consideration when approving the final rule changes in August.

The Cancer Prevention and Research Institute of Texas (CPRIT or the Institute) proposes amendments to 25 Tex. Admin. Code §§ 703.3, 703.10, 703.14, and 703.25 related to Request for Applications modifications on the Institute's website, leave of absences, no cost extension requests review and approval, and approval of grantee budget changes and transfers..

Background and Justification

The proposed change to § 703.3(b) clarifies that when CPRIT modifies a published Request for Applications (RFA), the agency will post the modification on CPRIT's public website.

The proposed amendment to § 703.10(c)(22) requires pre-approval for a Principal Investigator, Program Director, or Company Representative's temporary leave of absence. The proposed change ensures that appropriate leadership is maintained for the CPRIT-funded project.

The proposed change to § 703.14(c)(3) eliminates automatic approval of a grantee's first no cost extension. The rule currently allows for automatic approval of a grantee's first no cost extension if the term is six months or less and the grantee is in good fiscal and programmatic standing. CPRIT proposes the change so that the agency may consider whether extenuating circumstances weigh against extending the project term.

Lastly, the proposed amendment to § 703.25(e) clarifies when a grantee may make a budget transfer or change without prior approval from CPRIT. Preapproval is not necessary when the total dollar amount of the changes within budget categories other than equipment is 10% or less of the total budget for the grant year. However, as set forth in the proposed amendment, CPRIT may reverse one or more budget changes not requiring preapproval if the changes made by the grantee, when considered together, exceed the threshold amount for CPRIT approval.

Fiscal Note

Kristen Pauling Doyle, Deputy Executive Officer and General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule changes are in effect, there will be no foreseeable implications relating to costs or revenues for state or local government due to enforcing or administering the rules.

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule changes are in effect the public benefit anticipated due to enforcing the rule will be clarifying processes regarding grant review, specifying information to be included in single audit reviews, and specifying additional categories of unallowable expenses.

Small Business, Micro-Business, and Rural Communities Impact Analysis

Ms. Doyle has determined that the rule changes will not affect small businesses, micro businesses, or rural communities.

Government Growth Impact Statement

The Institute, in accordance with 34 Texas Administrative Code §11.1, has determined that during the first five years that the proposed rule changes will be in effect:

(1) the proposed rule changes will not create or eliminate a government program;

(2) implementation of the proposed rule changes will not affect the number of employee positions;

(3) implementation of the proposed rule changes will not require an increase or decrease in future legislative appropriations;

(4) the proposed rule changes will not affect fees paid to the agency;

(5) the proposed rule changes will not create new rules;

(6) the proposed rule changes will not expand existing rules;

(7) the proposed rule changes will not change the number of individuals subject to the rules; and

(8) The rule changes are unlikely to have a significant impact on the state's economy. Although these changes are likely to have neutral impact on the state's economy, the Institute lacks enough data to predict the impact with certainty.

Submit written comments on the proposed rule changes to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than July 1, 2019. The Institute asks parties filing comments to indicate whether they support the rule revisions proposed by the Institute and, if a change is requested, to provide specific text proposed to be included in the rule. Comments may be submitted electronically to kdoyle@cprit.texas.gov. Comments may be submitted by facsimile transmission to 512/475-2563.

Statutory Authority

The Institute proposes the rule changes under the authority of the Texas Health and Safety Code Annotated, §102.108, which provides the Institute with broad rule-making authority to administer the chapter. Ms. Doyle has reviewed the proposed amendments and certifies the proposal to be within the Institute’s authority to adopt.

There is no other statute, article, or code affected by these rules.

<rule>

§703.3 Grant Applications

(a) The Institute shall accept Grant Applications for Cancer Research and Cancer Prevention programs to be funded by the Cancer Prevention and Research Fund or the proceeds of general obligation bonds issued on behalf of the Institute in response to standard format Requests for Applications issued by the Institute.

(b) Each Request for Applications shall be publicly available through the Institute's Internet website. The Institute reserves the right to modify the format and content requirements for the Requests for Applications from time to time. ~~Notice of~~ Any modifications will be ~~announced and~~ available through the Institute's Internet website. The Request for Applications shall:

(1) Include guidelines for the proposed projects and may be accompanied by instructions provided by the Institute.

(2) State the criteria to be used during the Grant Review Process to evaluate the merit of the Grant Application, including guidance regarding the range of possible scores.

(A) The specific criteria and scoring guidance shall be developed by the Chief Program Officer in consultation with the Review Council.

(B) When the Institute will use a preliminary evaluation process as described in §703.6 of this chapter (relating to Grant Review Process) for the Grant Applications submitted pursuant to a particular Grant Mechanism, the Request for Applications shall state the criteria and Grant Application components to be included in the preliminary evaluation.

(3) Specify limits, if any, on the number of Grant Applications that may be submitted by an entity for a particular Grant Mechanism to ensure timely and high-quality review when a large number of Grant Applications are anticipated.

(c) Requests for Applications for Cancer Research and Cancer Prevention projects issued by the Institute may address, but are not limited to, the following areas:

(1) Basic research;

(2) Translational research, including proof of concept, preclinical, and Product Development activities;

(3) Clinical research;

(4) Population based research;

(5) Training;

(6) Recruitment to the state of researchers and clinicians with innovative Cancer Research approaches;

(7) Infrastructure, including centers, core facilities, and shared instrumentation;

(8) Implementation of the Texas Cancer Plan; and

(9) Evidence based Cancer Prevention education, outreach, and training, and clinical programs and services.

(d) An otherwise qualified applicant is eligible solely for the Grant Mechanism specified by the Request for Applications under which the Grant Application was submitted.

(e) The Institute may limit the number of times a Grant Application not recommended for a Grant Award during a previous Grant Review Cycle may be resubmitted in a subsequent Grant Review Cycle. The Request for Applications will state the resubmission guidelines, including specific instructions for resubmissions.

(f) Failure to comply with the material and substantive requirements set forth in the Request for Applications may serve as grounds for disqualification from further consideration of the Grant Application by the Institute. A Grant Application determined by the Institute to be incomplete or otherwise noncompliant with the terms or instructions set forth by the Request for Applications shall not be eligible for consideration of a Grant Award.

(g) Only those Grant Applications submitted via the designated electronic portal designated by the Institute by the deadline, if any, stated in the Request for Applications shall be eligible for consideration of a Grant Award.

(1) Nothing herein shall prohibit the Institute from extending the submission deadline for one or more Grant Applications upon a showing of good cause, as determined by the Chief Program Officer.

(2) A request to extend the Grant Application submission deadline must be in writing and sent to the CPRIT Helpdesk via electronic mail, within 24 hours of the submission deadline.

(3) The Institute shall document any deadline extension granted, including the good cause for extending the deadline and will cause the documentation to be maintained as part of the Grant Review Process records.

(h) The Grant Applicant shall certify that it has not made and will not make a donation to the Institute or any foundation created to benefit the Institute.

(1) Grant Applicants that make a donation to the Institute or any foundation created to benefit the Institute on or after June 14, 2013, are ineligible to be considered for a Grant Award.

(2) For purposes of the required certification, the Grant Applicant includes the following individuals or the spouse or dependent child(ren) of the following individuals:

(A) the Principal Investigator, Program Director, or Company Representative;

(B) a Senior Member or Key Personnel listed on the Grant Application; and

(C) an officer or director of the Grant Applicant.

(3) Notwithstanding the foregoing, one or more donations exceeding $500 by an employee of a Grant Applicant not described by paragraph (2) of this subsection shall be considered to be made on behalf of the Grant Applicant for purposes of the certification.

(4) The certification shall be made at the time the Grant Application is submitted.

(5) The Chief Compliance Officer shall compare the list of Grant Applicants to a current list of donors to the Institute and any foundation created to benefit the Institute.

(6) To the extent that the Chief Compliance Officer has reason to believe that a Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, the Chief Compliance Officer shall seek information from the Grant Applicant to resolve any issue. The Grant Application may continue in the Grant Review Process during the time the additional information is sought and under review by the Institute.

(7) If the Chief Compliance Officer determines that the Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, then the Institute shall take appropriate action. Appropriate action may entail:

(A) Withdrawal of the Grant Application from further consideration; or

(B) Return of the donation, if the return of the donation is possible without impairing Institute operations.

(8) If the donation is returned to the Applicant, then the Grant Application is eligible to be considered for a Grant Award.

(i) Grant Applicants shall identify by name all sources of funding contributing to the project proposed for a Grant Award. A Grant Applicant for a Product Development Research Grant Award must provide a capitalization table that includes those individuals or entities that have an investment, stock or rights in the company. The Institute shall make the information provided by the Grant Applicant available to Scientific Research and Prevention Programs Committee members, Institute employees, independent contractors participating in the Grant Review Process, Program Integration Committee Members and Oversight Committee Members for purposes of identifying potential Conflicts of Interest prior to reviewing or taking action on the Grant Application. The information shall be maintained in the Institute's Grant Review Process records.

(j) A Grant Applicant shall indicate if the Grant Applicant is currently ineligible to receive Federal or State grant funds due to debarment or suspension or if the Grant Applicant has had a grant terminated for cause within five years prior to the submission date of the Grant Application. For purposes of the provision, the term Grant Applicant includes the personnel, including collaborators or contractors, who will be working on the Grant Award. A Grant Applicant is not eligible to receive a Grant Award if the Grant Applicant is debarred, suspended, ineligible or otherwise excluded from participation in a federal or state grant award.

(k) The Institute may require each Grant Applicant for a Cancer Research Grant Award for Product Development to submit an application fee.

(1) The Chief Executive Officer shall adopt a policy regarding the application fee amount.

(2) The Institute shall use the application fee amounts to defray the Institute's costs associated with the Product Development review processes, including due diligence and intellectual property reviews, as specified in the Request for Application.

(3) Unless a request to submit the fee after the deadline has been approved by the Institute, the Institute may administratively withdraw a Grant Application if the application review fee is not

received by the Institute within seven business days of the Grant Application submission deadline.

(4) Upon a written request from the Grant Applicant, the Institute may refund the application fee to the Grant Applicant if the Grant Applicant withdraws the Grant Application or the Grant Application is otherwise removed from the Grant Review Process prior to the review of the Grant Application by the Scientific Research and Prevention Programs Committees. The Institute's decision regarding return of the application fee is final.

(l) During the course of administrative review of the Grant Application, the Institute may contact the Grant Applicant to seek clarification on information provided in the Grant Application or to request additional information if such information clarifies the Grant Application. The Institute shall keep a record of requests made under this subsection for review by the Chief Compliance Officer.

§ 703.10 Awarding Grants by Contract

(a) The Oversight Committee shall negotiate on behalf of the state regarding the awarding of grant funds and enter into a written contract with the Grant Recipient.

(b) The Oversight Committee may delegate Grant Contract negotiation duties to the Chief Executive Officer and the General Counsel for the Institute. The Chief Executive Officer may enter into a written contract with the Grant Recipient on behalf of the Oversight Committee.

(c) The Grant Contract shall include the following provisions:

(1) If any portion of the Grant Contract has been approved by the Oversight Committee to be used to build a capital improvement, the Grant Contract shall specify that:

(A) The state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award amount used to pay for the capital improvement; and

(B) If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale;

(2) Terms relating to Intellectual Property Rights and the sharing with the Institute of revenues generated by the sale, license, or other conveyance of such Project Results consistent with the standards established by this chapter;

(3) Terms relating to publication of materials created with Grant Award funds or related to the Cancer Research or Cancer Prevention project that is the subject of the Grant Award, including an acknowledgement of Institute funding and copyright ownership, if applicable;

(4) Repayment terms, including interest rates, to be enforced if the Grant Recipient has not used Grant Award funds for the purposes for which the Grant Award was intended;

(5) A statement that the Institute does not assume responsibility for the conduct of the Cancer Research or Cancer Prevention project, and that the conduct of the project and activities of all investigators are under the scope and direction of the Grant Recipient;

(6) A statement that the Cancer Research or Cancer Prevention project is conducted with full consideration for the ethical and medical implications of the project and that the project will comply with all federal and state laws regarding the conduct of the Cancer Research or Prevention project;

(7) Terms related to the Standards established by the Oversight Committee in Chapter 701 of this title (relating to Policies and Procedures) to ensure that Grant Recipients, to the extent reasonably possible, demonstrate good faith effort to purchase goods and services for the Grant Award project from suppliers in this state and from historically underutilized businesses as defined by Chapter 2161, Texas Government Code, and any other state law;

(8) An agreement by the Grant Recipient to submit to regular inspection reviews of the Grant Award project by Institute staff during normal business hours and upon reasonable notice to ensure compliance with the terms of the Grant Contract and continued merit of the project;

(9) An agreement by the Grant Recipient to submit Grant Progress Reports to the Institute on a schedule specified by the Grant Contract that include information on a grant-by-grant basis quantifying the amount of additional research funding, if any, secured as a result of Institute funding;

(10) An agreement that, to the extent possible, the Grant Recipient will evaluate whether any new or expanded preclinical testing, clinical trials, Product Development, or manufacturing of any real or intellectual property resulting from the award can be conducted in this state, including the establishment of facilities to meet this purpose;

(11) An agreement that the Grant Recipient will abide by the Uniform Grant Management Standards (UGMS) adopted by the Governor's Office, if applicable unless one or more standards conflicts with a provision of the Grant Contract, Chapter 102, Texas Health and Safety Code, or the Institute's administrative rules. Such interpretation of the Institute rules and UGMS shall be made by the Institute;

(12) An agreement that the Grant Recipient is under a continuing obligation to notify the Institute of any adverse conditions that materially impact milestones and objectives included in the Grant Contract;

(13) An agreement that the design, conduct, and reporting of the Cancer Research or Prevention project will not be biased by conflicting financial interest of the Grant Recipient or any individuals associated with the Grant Award. This duty is fulfilled by certifying that an appropriate written, enforced Conflict of Interest policy governs the Grant Recipient.

(14) An agreement regarding the amount, schedule, and requirements for payment of Grant Award funds, if such advance payments are approved by the Oversight Committee in accordance with this chapter. Notwithstanding the foregoing, the Institute may require that up to ten percent

of the final tranche of funds approved for the Grant Award must be expended on a reimbursement basis. Such reimbursement payment shall not be made until close out documents described in this section and required by the Grant Contract have been submitted and approved by the Institute;

(15) An agreement to provide quarterly Financial Status Reports and supporting documentation for expenses submitted for reimbursement or, if appropriate, to demonstrate how advanced funds were expended;

(16) A statement certifying that, as of June 14, 2013, the Grant Recipient has not made and will not make a contribution, during the term of the Grant Contract, to the Institute or to any foundation established specifically to support the Institute;

(17) A statement specifying the agreed effective date of the Grant Contract and the period in which the Grant Award funds must be spent. If the effective date specified in the Grant Contract is different from the date the Grant Contract is signed by both parties, then the effective date shall control;

(18) A statement providing for reimbursement with Grant Award funds of expenses made prior to the effective date of the Grant Contract at the discretion of the Institute. Pre-contract reimbursement shall be made only in the event that:

(A) The expenses are allowable pursuant to the terms of the Grant Contract;

(B) The request is made in writing by the Grant Recipient and approved by the Chief Executive Officer; and

(C) The expenses to be reimbursed were incurred on or after the date the Grant Award recommendation was approved by the Oversight Committee.

(19) Requirements for closing out the Grant Contract at the termination date, including the submission of a Financial Status Report, a final Grant Progress Report, a equipment inventory, a HUB and Texas Business report, a revenue sharing form, a single audit determination report form and a list of contractual terms that extend beyond the termination date;

(20) A certification of dedicated Matching Funds equal to one-half of the amount of the Research Grant Award that includes the name of the Research Grant Award to which the matching funds are to be dedicated, as specified in Section §703.11 of this chapter (relating to Requirement to Demonstrate Available Funds for Cancer Research Grants);

(21) The project deliverables as described by the Grant Application and stated in the Scope of Work for the Grant Contract reflecting modifications, if any, approved during the Peer Review process or during Grant Contract negotiation; and

(22) An agreement that the Grant Recipient shall notify the Institute and seek approval for a change in effort for any of the Senior Members or Key Personnel of the research or prevention team listed on the Grant Application, including any proposed temporary leave of absence of a Principal Investigator, Program Director, or Company Representative.

(23) An agreement that the Grant Recipient is legally responsible for the integrity of the fiscal and programmatic management of the organization.

(24) An agreement that the Grant Recipient is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. The Grant Recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing the Institute if the infraction is related to a Grant Award.

(d) The Grant Recipient's failure to comply with the terms and conditions of the Grant Contract may result in termination of the Grant Contract pursuant to the process prescribed in the Grant Contract and trigger repayment of the Grant Award funds

§703.14 Termination, Extension, Close Out of Grant Contracts, and De-Obligation of Grant Award Funds

(a) The termination date of a Grant Contract shall be the date stated in the Grant Contract, except:

(1) The Chief Executive Officer may elect to terminate the Grant Contract earlier because the Grant Recipient has failed to fulfill contractual obligations, including timely submission of required reports or certifications;

(2) The Institute terminates the Grant Contract because funds allocated to the Grant Award are reduced, depleted, or unavailable during the award period, and the Institute is unable to obtain additional funds for such purposes; or

(3) The Institute and the Grant Recipient mutually agree to terminate the Grant Contract earlier.

(b) If the Institute elects to terminate the Grant Contract pursuant to subsection (a)(1) or (2) of this section, then the Chief Executive Officer shall notify the Grant Recipient in writing of the intent to terminate funding at least thirty (30) days before the intended termination date. The notice shall state the reasons for termination, and the procedure and time period for seeking reconsideration of the decision to terminate. Nothing herein restricts the Institute's ability to terminate the Grant Contract immediately or to seek additional remedies if justified by the circumstances of the event leading to early termination.

(c) The Institute may approve the Grant Recipient's written request to extend the termination date of the Grant Contract to permit the Grant Recipient additional time to complete the work of the project.

(1) A no cost extension may be granted if the Grant Recipient is in good fiscal and programmatic standing. The Institute's decision to approve or deny a no cost extension request is final.

(2) The Grant Recipient may request a no cost extension no earlier than 180 days and no later than thirty (30) days prior to the termination date of the Grant Contract.

(A) If a Grant Recipient fails to request a no cost extension within the required timeframe, the Grant Recipient may petition the Chief Executive Officer in writing to consider the no cost extension. The Grant Recipient's petition must show good cause for failing to submit the request within the timeframe specified in subsection (c) of this section.

(B) Upon a finding of good cause, the Chief Executive Officer may consider the request. If a no cost extension request is approved under this subsection, the Chief Executive Officer must notify the Oversight Committee in writing and provide justification for the approval.

(3) The Institute may approve one or more no cost extensions. The duration of each no cost extension may be no longer than six months from the termination date of the Grant Contract, unless the Institute finds that special circumstances justify authorizing additional time to complete the work of the project.

S~~(A) The Grant Recipient's first no cost extension that is less than or equal to six months will be approved so long as the Grant Recipient is in good fiscal and programmatic standing~~U~~.~~

S~~(B)~~S If a grant recipient requests a second no cost extension or requests a no cost extension greater than six months, the grantee must provide good cause for approving the request.

(4) If the Institute approves the request to extend the termination date of the Grant Contract, then the termination date shall be amended to reflect the change.

(5) Nothing herein prohibits the Institute and the Grant Recipient from taking action more than 180 days prior to the termination date of the Grant contract to extend the termination date of the Grant Contract. Approval of an extension must be supported by a finding of good cause and the Grant Contract shall be amended to reflect the change.

(d) The Grant Recipient must submit a final Financial Status Report and final Grant Progress Report as well as any other required reports as specified in the Grant Contract. For purposes of this rule, the final Grant Progress Report and other required reports shall be collectively referred to as "close out documents."

(1) The final Financial Status Report shall be submitted to the Institute within ninety (90) days of the end of the state fiscal quarter that includes the termination date of the Grant Contract. The Grant Recipient's failure to submit the Financial Status report within thirty (30) days following the due date specified in this subsection will waive reimbursement of project costs incurred during the reporting period. The Institute may approve additional time to submit the final Financial Status Report if the Grant Recipient can show good cause for failing to timely submit the final Financial Status Report.

(2) Close out documents must be submitted within ninety (90) days of the termination date of the Grant Contract. The final reimbursement payment shall not be made until all close out documents have been submitted and approved by the Institute. Failure to submit one or more close out documents within 180 days of the Grant Contract termination date shall result in the Grant Recipient being ineligible to receive new Grant Awards or continuation Grant Awards

until such time that the close out documents are submitted unless the Institute waives the final submission of close out documents by the Grant Recipient.

(A) Approval of the Grant Recipient's request to waive the submission of close out documents is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(B) The Oversight Committee shall be notified in writing of the Grant Recipient's waiver request and the Chief Executive Officer's decision to approve or reject the waiver request.

(C) Unless the Oversight Committee votes by a simple majority of members present and able to vote to overturn the Chief Executive Officer's decision regarding the waiver, the Chief Executive Officer's decision shall be considered final.

(e) The Institute may make upward or downward adjustments to the Allowable Costs requested by the Grant Recipient within ninety (90) days following the approval of the close out reports or the final Financial Status Report, whichever is later.

(f) Nothing herein shall affect the Institute's right to disallow costs and recover Grant Award funds on the basis of a later audit or other review or the Grant Recipient's obligation to return Grant Award funds owed as a result of a later refund, correction, or other transaction.

(g) Any Grant Award funds paid to the Grant Recipient in excess of the amount to which the Grant Recipient is finally determined to be entitled under the terms of the Grant Contract constitute a debt to the state. If not paid within a reasonable period after demand, the Institute may reduce the debt owed by:

(1) Making an administrative offset against other requests for reimbursements;

(2) Withholding advance payments otherwise due to the Grant Recipient; or

(3) Other action permitted by law.

(h) Grant Award funds approved by the Oversight Committee and specified in the Grant Contract but not spent by the Grant Recipient at the time that the Grant Contract is terminated are considered de-obligated for the purposes of calculating the maximum amount of annual Grant Awards and the total amount authorized by Section 67, Article III, Texas Constitution. Such de-obligated funds are available for all purposes authorized by the statute.

(i) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§703.25 Grant Award Budget

(a) The Grant Contract shall include an Approved Budget that reflects the amount of the Grant Award funds to be spent for each Project Year.

(b) All expenses charged to a Grant Award must be budgeted and reported in the appropriate budget category.

(c) Actual expenditures under each category should not exceed budgeted amounts authorized by the Grant Contract as reflected on the Approved Budget for each Grant Award.

(d) Recipients may make transfers between or among lines within budget categories listed on the Approved Budget so long as the transfer fits within the scope of the Grant Contract and the total Approved Budget; is beneficial to the achievement of project objectives; and is an efficient, effective use of Grant Award funds.

(e) Except as provided herein, ~~A~~all budget changes or transfers require Institute approval~~, except that the Grant Recipient may make budget changes or transfers without prior approval from the Institute for expenses not specified in the equipment category if:~~

~~(1) The total dollar amount of all changes of any single line item (individually and in the aggregate) within budget categories other than equipment is not more than 10% of the amount in that line item;~~

~~(2) The transfer will not increase or decrease the total grant budget; and~~

~~(3) The transfer will not materially change the nature, performance level, or scope of the project~~.

(1) The Grant Recipient may make budget changes or transfers without prior approval from the Institute for expenses not specified in the equipment category if:
   (a) The total dollar amount of all changes of any single line item (individually and in the aggregate) within budget categories other than equipment is 10% or less of the total budget for the applicant grant year;
   (b) The transfer will not increase or decrease the total grant budget; and
   (c) The transfer will not materially change the nature, performance level, or scope of the project.
(2) The Institute may reverse one or more budget changes or transfers under subsection (1) if the Institute determines that the Grant Recipient made multiple individual budget changes or transfers within the same category that, if considered together, would require Institute approval.

(f) A Grant Recipient awarded a Grant Award for a multiyear project that fails to expend the total Project Year budget may carry forward the unexpended budget balance to the next Project Year.

(1) If the amount of the unexpended balance for a budget line item in a Project Year exceeds twenty-five percent (25%) or more of the total budget line item amount for that year, Institute approval is required before the Grant Recipient may carry forward the unexpended balance to the next Project Year.

(2) For a budget carry forward requiring Institute approval, the Grant Recipient must provide justification for why the total Grant Award amount should not be reduced by the unexpended balance.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	CHIEF OPERATING OFFICER REPORT FOR FY 2019, QUARTER 2
DATE:	MAY 6, 2019

CPRIT Financial Overview for FY 2019, Quarter 2

FY 2019, Quarter 2 Operating Budget

CPRIT expended or obligated approximately $2.1 million in Indirect Administration and approximately $11.9 million in Grant Review and Award Operations, or approximately 79% of the overall $16.7 million administrative budget for the fiscal year. The majority of the budget expenditures and obligations fall into two categories, employee salaries and service contracts. The operating budget incorporates the $547,031 transfer approved by the Legislative Budget Board in November 2018 from the Research Grant budget line item to the administrative budget line item for IT infrastructure security items.

During the second quarter, the agency received $47,500 in revenue sharing payments for a total of $205,552 received through the end of February 2019. The total revenue sharing payments received to date is approaching $3.7 million.

FY 2019, Quarter 2 Performance Measure Report

CPRIT reported second quarter performance to the Legislative Budget Board on the two output measures with quarterly reporting requirements:

1) Number of Cancer Prevention and Control Services Provided, and
2) Number of Entities Relocating to Texas for Cancer Research Related Projects.

Debt Issuance History

CPRIT did not request Texas Public Finance Authority (TPFA) issue additional general obligation debt in the second quarter because the $75,975,000 of general obligation bonds issued in September 2018 covered grant reimbursement expenses through this period.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of February 28, 2019

Indirect Administration (B.1.1.)

		2019 Appropriated	2019 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,617,425	$ 1,525,975		$ 674,177	851,799	44%	$ 674,177	$ 851,799
1002	Other Personnel Costs	38,785	135,816		10,043	125,773	7%	10,043	125,773
2001	Professional Fees and Services	961,664	1,504,614		1,066,591	438,022	71%	1,066,591	438,022
2003	Consumable Supplies	24,000	24,000		10,968	13,032	46%	10,968	13,032
2004	Utilities	58,600	58,600		41,972	16,628	72%	41,972	16,628
2005	Travel	45,000	45,000		24,514	20,486	54%	24,514	20,486
2006	Rent-Building	13,700	22,093		22,093	0	0%	22,093	0
2007	Rent-Machine and Other	32,172	32,172		5,946	26,226	18%	5,946	26,226
2009	Other Operating Expenses	473,815	463,922		263,160	200,762	57%	263,160	200,762
	Subtotal - Indirect Administration (B.1.1.)	**$ 3,265,161**	**$ 3,812,192**	**1.28%**	**$ 2,119,465**	**$ 1,692,727**	**56%**	**$ 2,119,465**	**$ 1,692,727**

Grant Review and Award Operations (A.1.3.)

		2019 Appropriated	2019 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 3,078,084	3,078,084		$ 1,621,615	$ 1,456,469	53%	$ 1,621,615	$ 1,456,469
1002	Other Personnel Costs	45,500	45,500		45,228	272	0%	45,228	272
2001	Professional Fees and Services	10,151,277	10,904,364		10,166,444	737,921	93%	10,166,444	737,921
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities	12,000	12,000		6,140	5,860	51%	6,140	5,860
2005	Travel	65,000	65,000		23,693	41,307	36%	23,693	41,307
2009	Other Operating Expenses	102,730	96,680		28,790	67,890	30%	28,790	67,890
	Subtotal - Grant Operations (A.1.3.)	**$ 13,454,591**	**$ 14,201,628**	**4.77%**	**$ 11,891,910**	**$ 2,309,718**	**84%**	**$ 11,891,910**	**$ 2,309,718**

Grants

		2019 Appropriated	2019 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 28,037,956	$ 28,037,956		$ -	$ 28,037,956	0%	$ -	$ 28,037,956
4000	Grants - Research (A.1.1.)	252,327,738	$ 251,780,707		16,000,000	$ 235,780,707	6%	16,000,000	235,780,707
	Subtotal - Grants	**$ 280,365,694**	**$ 279,818,663**	**93.95%**	**$ 16,000,000**	**$ 263,818,663**	**6%**	**$ 16,000,000**	**$ 263,818,663**
	Grand Totals	**$ 297,085,446**	**$ 297,832,483**	**100.00%**	**$ 30,011,374**	**$ 267,821,109**	**10%**	**$ 30,011,374**	**$ 267,821,109**

Cancer Prevention and Research Institute of Texas
FY 2019, Quarter 2 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	500,000	223,464	241,337			464,801	92.96%
Number of Entities Relocating to TX for Cancer Research Related Projects	2	0	0			0	0.00%
Annual Age-adjusted Cancer Mortality Rate	156.8	N/A	N/A	N/A	N/A		0.00%
Number of Published Articles on CPRIT-Funded Research Projects	900	N/A	N/A	N/A	N/A		0.00%
Number of New Jobs Created and Maintained	1,335	N/A	N/A	N/A	N/A		0.00%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
CPRIT grantees deliver education and clinical services throughout the year, so the reported number of people served is not allocated evenly for each fiscal quarter.
Number of Entities Relocating to TX for Cancer Research Related Projects
This output is dependent on the number of companies applying for CPRIT Company Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	$ 225,000,000	September 9, 2009	$ 9,100,000		Commercial Paper Notes	Series A, Taxable		
2010		September 9, 2009	$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	$ 63,800,000		Commercial Paper Notes	Series A, Taxable		
2010		August 26, 2010	$ 148,500,000		Commercial Paper Notes	Series A, Taxable		
				$ 225,000,000				
2011	$ 225,000,000	September 7, 2010	$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	$ 51,000,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded $233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				$ 62,800,000				
2012	$ 300,000,000	September 7, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		December 8, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		March 2, 2012	$ 12,300,000		Commercial Paper Notes	Series A, Taxable		
2012		June 21, 2012	$ 15,000,000		Commercial Paper Notes	Series A, Taxable		
2012		August 16, 2012	$ 42,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 75,700,000				
2013	$ 300,000,000	September 6, 2012	$ 9,600,000		Commercial Paper Notes	Series A, Taxable		
2013		May 16,2013	$ 13,400,000		Commercial Paper Notes	Series A, Taxable		
				$ 23,000,000				
2014	$ 300,000,000	November 25, 2013	$ 55,200,000		Commercial Paper Notes	Series A, Taxable		
2014		March 13, 2014	$ 47,000,000		Commercial Paper Notes	Series A, Taxable		
2014		June 17, 2014	$ 60,300,000		Commercial Paper Notes	Series A, Taxable		
2014		July 8, 2014	$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded $237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				$ 162,500,000				
2015	$ 300,000,000	November 5, 2014	$ 57,600,000		Commercial Paper Notes	Series A, Taxable		
2015		April 29, 2014	$ 112,000,000		Commercial Paper Notes	Series A, Taxable		
2015		June 26, 2015	$ 75,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 244,600,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2016	$ 300,000,000	September 22, 2015	$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded $300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Par amount of new money: Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		May 16, 2016	$ 92,100,000		Commercial Paper Notes	Series A, Taxable		
2016		August 29, 2016	$ 60,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 277,300,000				
2017	$300,000,000	October 19, 2016	$ 58,000,000		Commercial Paper Notes	Series A, Taxable		
2017		January 5, 2017	$ 58,900,000		Commercial Paper Notes	Series A, Taxable		
2017		February 8, 2017	$ 269,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2017	Par amount of refunding: Refunded $269M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.4622%
2017		February 8, 2017	$ 106,000,000		G.O. Bonds	Taxable Series 2017	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.4622 %
				$ 222,900,000				
2018	$300,000,000	September 29, 2017	$ 68,200,000		Commercial Paper Notes	Series A, Taxable		
2018		March 8, 2018	$ 99,000,000		Commercial Paper Notes	Series A, Taxable		
2018		July 11, 2018	$ 55,000,000		Commercial Paper Notes	Series A, Taxable		
2019		September 11, 2018	$ 222,200,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2018	Par amount of refunding	Fixed Rate Bonds All-in-True Interest Cost 3.720609%
				$ 222,200,000				
2019	$300,000,000	September 11, 2018	$ 75,975,000		G.O. Bonds	Taxable Series 2018	Par amount of new money	Fixed Rate Bonds All-in-True Interest Cost 3.720609%
				$ 75,975,000				
TOTAL ISSUED TO DATE				**$ 1,591,975,000**				

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**HEIDI MCCONNELL, CHIEF OPERATING OFFICER**
Subject:	**FY 2020 REQUEST FOR FINANCING OF CPRIT BONDS**
Date:	**MAY 6, 2019**

Recommendation

CPRIT staff recommends that the Oversight Committee approve the attached resolution for a request for financing to the Texas Public Finance Authority (TPFA) to issue debt on behalf of CPRIT in fiscal year 2020. The amount to be financed will not exceed $300 million in bond proceeds appropriated to CPRIT for its operations and prevention and research grant awards. I estimate that CPRIT will request TPFA issue $231.3 million in commercial paper notes four times during fiscal year 2020 to pay for CPRIT administrative operations and grant reimbursements or authorized advances related to awards made in fiscal years 2013, 2014, 2015, 2016, 2017, 2018 2019, and 2020.

Background

Through the Texas Public Finance Authority (TPFA), 207.7 million in general obligation debt has or will be issued for fiscal year 2019 agency operations and grant award expenses. TPFA has issued approximately $1.5 billion in long-term general obligation bonds for debt CPRIT incurred from fiscal years 2010 through 2019.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

A RESOLUTION
AUTHORIZING A REQUEST FOR FINANCING
AND THE EXECUTION AND DELIVERY OF DOCUMENTS
REQUIRED TO EFFECT SUCH FINANCING

Whereas, the Texas Public Finance Authority (the "Authority") is authorized to issue general obligation bonds to finance the grant program for cancer research and prevention and control for the use and benefit of the Cancer Prevention & Research Institute of Texas (the "Agency") pursuant to Article III, Section 67, Texas Constitution; Texas Health & Safety Code, Chapter 102, as amended; and Texas Government Code, Chapter 1232, as amended, (collectively, the "Authorizing Law");

Whereas, the Agency desires and intends to request the Authority to finance the costs of the program as permitted by the Authorizing Law; and

Whereas, the Agency recognizes that in order to finance the cost of the program, the Authority may issue short term obligations, general obligation bonds, either or both ("Obligations") in an aggregate principal amount sufficient to finance program costs in an amount not to exceed $300,000,000, plus the costs of issuance and related administrative costs, if any, which will be determined at the time of issuance; and

Whereas, the form of a Request for Financing, dated as of May 15, 2019, (the "Request for Financing") from the Agency to the Authority, which includes a detailed description of the program to be financed for the Agency ("program" herein) and a proposed expenditure schedule is presently before the CPRIT Oversight Committee.

NOW THEREFORE BE IT RESOLVED by the CPRIT Oversight Committee that:

Section 1. The purpose of the financing is to provide funds sufficient to make grant awards for cancer research and prevention and control and for the operations of the Agency, and the financing thereof is appropriate at this time. Accordingly, the execution and delivery of the Request for Financing to the Authority pursuant to the Authorizing Law is hereby ratified, approved and confirmed.

Section 2. The Chief Executive Officer of the Agency is hereby empowered, authorized and directed to:

a. sign and deliver any and all documents necessary or desirable to effect the financing and provide the projects, which may include but not be limited to a Memorandum of Understanding and a Financing Agreement between the Agency and the Authority;

b. cooperate with the Authority and its consultants to prepare an Official Statement in connection with the sale of the Obligations;
c. and to take any other action necessary to assist in such sale.

Section 3. All actions not inconsistent with provisions of this Resolution heretofore taken by the Institute and the Chief Executive Officer or designee thereof and the other officers of, or consultants to the Institute, directed toward the financing of the Program, and the issuance of the Obligations are hereby ratified, approved and confirmed.

Section 4. The officers and employees of the Agency shall take all action in conformity with the Authorizing Law and the provisions of the General Appropriations Act, 86th Legislature, R.S. (2019) to effect the issuance of the Obligations and complete the Program as provided in the Agreement and take all action necessary or desirable or in conformity with the Authorizing Law for carrying out, giving effect to, and consummating the transactions contemplated by the Memorandum of Understanding, the Agreement, the Obligations, and this Request for Financing, including without limitation, the execution and delivery of any closing documents in connection with the closing of the Obligations.

Section 5. This Resolution was adopted at a meeting open to the public, and public notice of the time, place and purpose of said meeting was given, all as required by Ch. 551, Texas Government Code.

Adopted by the affirmative vote of a majority of the Cancer Prevention and Research Institute of Texas Oversight Committee present and voting on this 15th day of May, 2019.

Cancer Prevention and Research Institute
of Texas Oversight Committee

Attested:

Will Montgomery
Presiding Officer

Mahendra C. Patel, M.D.
Secretary

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Fiscal Year 2020 Request for Financing Program Description

Purpose

The Cancer Prevention and Research Institute of Texas (CPRIT) is the state agency mandated to:

1) create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;
2) attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and
3) develop and implement the Texas Cancer Plan.

Powers and Duties

CPRIT will make grants to provide funds to public or private persons to implement the Texas Cancer Plan, and make grants to institutions of learning and to advanced medical research facilities and collaborations in this state for:

1) research into the causes of and cures for all types of cancer in humans;
2) facilities for use in research into the causes of and cures for cancer;
3) research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer in humans; and
4) cancer prevention and control programs in this state to mitigate the incidence of all types of cancer in humans.

Implementation Plan

CPRIT estimates that $231.3 million in bonds proceeds must be issued on an as-needed basis consistent with Texas Government Code, Chapter 1232 to cover grant award obligations from fiscal years 2013, 2014, 2015, 2016, 2017, 2018, and 2019; new grant award obligations made during fiscal year 2020; and operating costs for general agency administration and pre- and post-award grants management processes.

During fiscal year 2020, CPRIT will use the bond proceeds to disburse grant funds for grants awarded by CPRIT during fiscal years 2013, 2014, 2015, 2016, 2017, 2018, and 2019. CPRIT is currently authorized to obligate approximately $201 million for cancer prevention and research grant awards in fiscal year 2020.

CPRIT announces grant awards for cancer prevention education and service programs and academic and product development cancer research programs four times per year. CPRIT anticipates that it will obligate all of the available $198 million for cancer prevention, product development research, and academic research.

Grant funds are generally disbursed quarterly on a reimbursement basis to grant recipients. For certain types of grant awards, limited to product development, CPRIT advances funds in order to provide those specific types of recipients with working capital to meet their research milestones or objectives.

CPRIT is authorized to use bond proceeds to fund its grant review and award operations and indirect administration costs. At this time, the approximate budgeted amount of these two categories is $17.5 million in bond proceeds for fiscal year 2020 based on the appropriations provided in both House Bill 1 and the Senate Committee Substitute for House Bill 1 of the 2020-21 Budget of 86th Legislature. From the total of all of the agency's operating costs, CPRIT requires half of the proceeds to be available at the beginning of the state fiscal year to be able to cover the operating expenses for six months. CPRIT anticipates the need for proceeds at the beginning of each state fiscal quarter to pay for award costs reimbursed to grant recipients for the previous state fiscal quarter.

The scientific research program provides awards in the following areas: cancer biology, cancer genetics, immunology, imaging, therapeutics, prevention/epidemiology, and informatics/ computation. The product development research program focuses awards on the development of cancer drugs, diagnostics, and devices based on discoveries made in one of the seven areas described above. Prevention program grants are awarded for cancer prevention information and services, early detection and treatment, professional education and practice, cancer data acquisition and utilization, or survivorship (the areas of the Texas Cancer Plan). Awards for all programs are issued for multiple years, ranging from two to five years.

CPRIT has established a grant process that allows grant proposals for cancer prevention, scientific research, and product development research to be submitted through requests for applications (RFA) issued throughout each fiscal year. All proposals are reviewed by multiple experts in the appropriate area. CPRIT has approximately 200 national experts in cancer prevention, research and product development to review proposals and provide funding recommendations to CPRIT.

The award recommendations developed by the peer review committees are forwarded to the Program Integration Committee (PIC) for consideration. The five members of the PIC are statutorily defined as the Chief Executive Officer (CEO), Chief Scientific Officer, Chief Prevention Officer, Chief Product Development Officer, and DSHS Commissioner. The PIC finalizes award recommendations across all programs prior to every Oversight Committee meeting. When those proposed awards are forwarded to the Oversight Committee, each recommended award is accompanied by an affidavit signed by the CEO to affirm that the award followed all required pre-award grant procedures. The Oversight Committee considers these recommendations and votes to approve the awards.

Fiscal Year	2010	2011	2012	2013^	2014	2015	2016	2017	2018	2019*	*2020***	*2021***	TOTAL
										in progress	*new biennium*		
GAA Line-Item Appropriations	**$ 225,000,000**	**$ 225,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	*$ 218,000,000*	*$ 218,000,000*	**$ 3,286,000,000**
BRB-Approved Constitutional Debt	**$ 225,000,000**	**$ 225,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**			**$ 2,850,000,000**
Total Value of Grant Awards Contracted	**$ 216,122,106**	**$ 210,651,285**	**$ 269,354,368**	**$ 105,493,808**	**$ 255,834,556**	**$ 269,707,850**	**$ 278,191,276**	**$ 272,030,746**	*$ 277,209,228*	$ -			$ 2,154,595,223
Agency Operations and Transfer to DSHS (Cancer Registry)	$ 8,866,523	$ 11,773,670	$ 18,591,666	$ 16,750,815	$ 20,492,668	$ 22,525,206	$ 20,341,154	$ 19,770,432	$ 19,707,288	*$ 20,196,337*	$ -	$ -	$ 205,015,759
Total Agency Expenses Obligated	$ 224,988,629	$ 222,424,955	$ 287,946,034	$ 122,244,623	$ 276,327,224	$ 292,233,056	$ 298,532,430	$ 291,801,178	$ 296,916,516	$ 20,196,337	$ -	$ -	$ 2,359,610,982
Issued Debt to Date	**$ 225,000,000**	**$ 217,176,041**	**$ 277,905,393**	**$ 120,738,319**	**$ 252,556,273**	**$ 229,156,960**	**$ 171,226,446**	**$ 105,631,893**	**$ 50,112,339**	*$ 20,196,337*	**$ -**	**$ -**	**$ 1,669,700,001**
Unobligated Bond Authority Appropriations	**$ -**	**$ 2,575,045**	**$ 12,053,966**	**$ 177,755,377**	**$ 23,672,776**	**$ 7,766,944**	**$ 1,467,570**	**$ 8,198,822**	**$ 3,083,484**	*$ 2,798,037*			**$ 239,372,021**
Remaining Balances in Closed Grant Contract (Available for Deobligation)	**$ 38,525,292**	**$ 9,032,975**	***$ 13,321,630***	***$ 3,397,268***	***$ 7,621,741***	***$ 4,846,577***	***$ 14,251***	$ -	$ -	$ -	**$ -**	**$ -**	**$ 76,759,734**
Unbudgeted ERS Cash Transfer for DSHS Retired Employee Insurance Payments	$ (10,779)	$ (11,953)	$ (103,591)	$ (91,534)	$ (134,151)	$ (129,694)	$ (139,609)	$ (156,337)	$ (166,003)	*$ (177,992)*	$ -	$ -	$ (1,121,643)

*Current state fiscal year

^State leadership moratorium on CPRIT grant awards.

**Projected appropriations based on $150 million in unappropriated constitutional bond authority and $286 million in unexpended bond authority balances (Rider 8, Special Printing to HB 1, House Engrossment, 86th Legislature, p. I-16). In addition to the amounts appropriated [herein and above], all amounts previously appropriated to the Cancer Prevention and Research Institute of Texas out of General Obligation Bond proceeds and awarded, obligated, or otherwise encumbered but not previously expended are apprpriated for the same purpose for the 2020-21 biennium beginning September 1, 2019.

Cancer Prevention and Research Institute of Texas

Estimated Expenditure Schedule, Fiscal Year 2020

Fiscal Year 2020	September	October	November	December	January	February	March	April	May	June	July	August	Total
Bond proceeds for Indirect Administration	$ 2,201,027	$ -	$ -	$ -	$ -	$ -	$ 2,201,026	$ -	$ -		$ -	$ -	$ 4,402,053
Bond proceeds for Grant Review and Award Operations	$ 6,432,365	$ -	$ -	$ -	$ -	$ -	$ 6,432,365	$ -	$ -	$ -	$ -	$ -	$ 12,864,730
Bond proceeds for Texas Cancer Registry (GAA 2018-19, Art. I, CPRIT Rider 5)	$ 1,484,777	$ -	$ -	$ -	$ -	$ -	$ 1,484,777	$ -	$ -	$ -	$ -	$ -	$ 2,969,554
Bond proceeds for Prevention and Research Grants	$ 54,300,000	$ -	$ -	$ 52,000,000	$ -	$ -	$ 51,500,000	$ -	$ -	$ 53,263,663	$ -	$ -	$ 211,063,663
Debt Issuance Subtotal, Fiscal Year 2019	$ 64,418,169	$ -	$ -	$ 52,000,000	$ -	$ -	$ 61,618,168	$ -	$ -	$ 53,263,663	$ -	$ -	$ 231,300,000
Cumulative Debt Total, Fiscal Year 2019	**$ 64,418,169**	**$ 64,418,169**	**$ 64,418,169**	**$ 116,418,169**	**$ 116,418,169**	**$ 116,418,169**	**$ 178,036,337**	**$ 178,036,337**	**$ 178,036,337**	**$ 231,300,000**	**$ 231,300,000**	**$ 231,300,000**	**$ 231,300,000**

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

To: **OVERSIGHT COMMITTEE MEMBERS**

From: **KRISTEN DOYLE, DEPUTY EXECUTIVE OFFICER AND GENERAL COUNSEL**

Subject: **FY 2019 DUE DILIGENCE SUPPORT SERVICES CONTRACT AMENDMENT**

Date: **MAY 8, 2019**

Recommendation

CPRIT staff and the Audit Subcommittee recommend that the agency amend the contract with ICON Clinical Research (ICON) for due diligence evaluation services with an increase to the budget of $57,475, which would change the not-to-exceed amount to $269,675 for FY 2019.

Background

The FY 2019 budget amount of $212,200 approved last year was based on ICON conducting eight diligence evaluations during the year. CPRIT pays only for completed reports at a per due diligence review unit cost of $26,525 for Texas Company and Relocation Company applications and $14,000 for Seed applications. The Product Development Review Council provides a "fund"/"do not fund" recommendation based largely on the diligence reports addressing these key issues.

Due diligence is a comprehensive assessment of the company prior to investment. ICON assesses diligence topics to assess likelihood of program success including:

- Discovery Science
- Preclinical Research
- Manufacturing
- Clinical Research
- Regulatory Approval
- Management and Financial
- Commercial

The number of product development applications CPRIT received in FY 2019 increased by more than 20% over previous years. As a result, the product development peer review panels recommended more applications for due diligence review in FY 2019 than originally projected. The product development review panels completed in-person presentations in April for the second review cycle of FY 2019 (19.2). The panels recommended four companies to move forward to due diligence. ICON completed nine due diligence reviews for the first review cycle of FY 2019. Without the proposed budget change, CPRIT will be unable to complete due diligence for the four 19.2 product development company applications currently pending review. After discussion with CPRIT staff, the Audit Subcommittee recommends the budget change.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	FY 2020 GRANT MANAGEMENT SUPPORT SERVICES CONTRACT RENEWAL APPROVAL
DATE:	MAY 6, 2019

Recommendation

CPRIT staff recommends that the agency exercise the third and final renewal option on our contract with SRA International, Inc., a CSRA Company (acquired by General Dynamics Information Technology in 2018) for a not to exceed amount of $7,957,810 in FY 2020. The contract is based on time and materials provided by CSRA so CPRIT only pays for actual services received from CSRA up to the contracted amount.

This pricing is based on the assumption CPRIT will have only one major grant review cycle for all of CPRIT's grant programs during FY 2020 due to the projected 2020-21 biennial budget ($218 million per year of the biennium) currently being considered by the 86th Texas Legislature which has not yet completed working out the differences between House (HB 1) and Senate (Committee Substitute to HB 1) versions of the budget in conference committee. If there are additional appropriations in the final version of the budget that allow the agency to have a second grant review cycle, CPRIT will seek approval for an amendment to increase the contract budget with CSRA for the support services necessary to complete another review cycle.

Background

CSRA provides:

- Logistical support for in-person and virtual peer review meetings;
- Summarized evaluation reports for each grant application including peer review chair consensus statements, budget recommendations, and noted issues in clinical trials with human subjects or animal research;
- Scientific expertise for the evaluation of the annual and final progress reports for academic research grants;
- A Software as a Service (SaaS) subscription to their Grants Management Platform (GMP) software including the application receipt module, program and peer review module, and grant management module;
- Enhancements to their GMP grants management module to increase protections over the data in that module as well as provide CPRIT the ability to reset workflows for certain reports when they are incorrectly submitted;

- Enhancements to their GMP program and peer review module to increase protections over the data in that module
- Incorporation of grant request for application requirements in the GMP application receipt module for electronic application submission; and
- Administration of electronic grant pedigrees.

CSRA has subcontracts with two Texas-based Historically Underutilized Business (HUB) vendors for some support services. One subcontractor, Innovation Event Management, provides meeting support services for the in-person peer review meetings held in Dallas or Houston. The other, The Alamo Travel Group, makes air travel arrangements for peer reviewers attending in-person meetings.

This renewal will require approval from the Legislative Budget Board (LBB) for CPRIT to finalize the FY 2020 contract.

CPRIT awarded a new contract to CSRA beginning in FY 2017 with a cost of $8,265,446 and exercised the first renewal option in FY 2018 at a cost of $8,995,852 and the second renewal in FY 2019 at a cost of 8,400,443.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE
FROM:	REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	2020 CPRIT CONFERENCE CATERING CONTRACT APPROVAL
DATE:	MAY 6, 2019

Recommendation
Staff recommends that the agency be authorized to finalize a contract with Austin Convention Center Catering for food and beverage banquet services up to $150,000 during the 2020 conference which will be held at the Austin Convention Center (ACC). The conference dates will be July 30-31, 2020. ACC requires the use of Austin Convention Center Catering for any food and beverage banquet services during events at the convention center.

The successful proposal from CPRIT's competitive January 14, 2019, Request for Proposal (RFP) was from the Fairmont Austin Hotel for room nights only with meeting space provided by the ACC.

Background
Austin Convention Center Catering provided an initial event estimate of $122,000. The final contract will be based on the number of conference attendees and actual menus selected. Based on previous conferences as well as to ensure there is a buffer for increases in menu items, $150,000 should be adequate for these expenses. These food and beverage banquet expenses must be paid entirely from conference registration fees.

Because the Fairmont Austin is providing only guest rooms and the ACC is providing meeting space, two other vendors must provide banquet services and audiovisual services separately at the ACC. Therefore, there will be four separate contracts for all services. ACC's preferred vendor for audiovisual services is Freeman Decorating. However, the other three contracts are not $100,000 or more, so do not require Oversight Committee approval.

The other three contracts are:

1. Austin Convention Center: Approximately $33,000 for all the meeting, poster exhibit and office space. CPRIT will use the meeting space conveniently located closest to the Fairmont hotel.
2. Freeman Decorating: An initial estimate should be available in the next two weeks as needs are still being discussed. AV costs will be finalized as the schedule and needs of the program are determined.

3. The Fairmont Hotel: There is no cost to CPRIT as conference participants will pay for guest rooms at the government per diem rate in effect in July 2020. The Fairmont is located directly across from the ACC and connected by a walkway. In addition to offering the government per diem rate, other concessions include a 25% discount on the standard parking rate and one (1) complimentary room for every 40 guest rooms booked. Mr. Roberts has signed the agreement with the Fairmont in order to secure the July 30-31, 2020, guest room block and other terms.

These are the largest conference expenses. An overall budget including faculty costs and other items will be presented to the Oversight Committee in August.

CPRIT issued two competitive Request for Proposals (RFP) for a conference venue. There were no responses to the first RFP, but CPRIT received two proposals to the second RFP issued on January 14, 2019. CPRIT notified hotels and convention and visitors bureaus in Austin, Dallas/Fort Worth, Houston and San Antonio about the RFP which was posted on the Electronic State Business Daily site.

CPRIT has held five conferences in the past, during the fall of 2010, 2011, 2012, 2015 and 2017. Each conference has attracted about 850 people.